

---

**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/28/2020 2:33:20 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Mark and Dale,

Following up – do you think I should b5?

Thanks!  
Rose

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

---

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Wednesday, February 26, 2020 11:42 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** FW: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Mark and Dale,

Should I b5? Let me know what you think.

Thanks!  
Rose

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Sent:** Monday, February 24, 2020 5:35 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>; manon.ress@cancerunion.org; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>  
**Subject:** Re: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dr. Freel, In the past 8 years or so, does the NIH ever limit the exclusivity term to something less than the life of a patent? And if not, why not?

REL0000024984

On Mon, Feb 24, 2020 at 4:55 PM Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)> wrote:

Dear Ms. Ardizzone,

Thank you for the jointly provided comments dated February 10, 2020 on the Prospective Grant of an Exclusive License to Stanford University for our co-owned invention related to Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2. The purpose of this proposed exclusive license is to consolidate rights from the three co-owner institutions with Stanford to allow them to take the lead in licensing the technology for commercial development on behalf of the co-owners.

Contrary to your comments in Part 1 of the "Discussion", the NIH does evaluate and consider the statutes and regulations under 35 U.S.C. § 209 and 37 C.F.R. § 404 for each contemplated exclusive license, including the conditions under 35 U.S.C. § 209(a)(1)-(2) as referenced in your comments. The license that is the subject of the referenced Notice is no exception to this review process and was reviewed and evaluated in light of the referenced statutes and regulations. Your questions and comments in Part 2 of the Discussion regarding the government's financial contribution to the development of the invention are not relevant to the criteria for the grant of an exclusive license. As I stated in my earlier email, this license has not yet been granted and therefore, the specific terms of the license are not yet set. Your recommendations regarding specific terms to be added to the license have been reviewed and noted. The remainder of your comments are either irrelevant to the criteria for granting an exclusive license or have been previously addressed by the NIH.

Best Regards,

Rose Freel

--

Rose Santangelo Freel, Ph.D.

Senior Technology Transfer Manager

**National Cancer Institute**

P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Monday, February 10, 2020 6:20 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; [manon.ress@cancerunion.org](mailto:manon.ress@cancerunion.org); Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>

REL0000024984

**Subject:** Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Dr. Freel:

Attached, please find the joint comments of Knowledge Ecology International, Union for Affordable Cancer Treatment, and Manon Ress, with respect to the "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2."

Thank you in advance for reviewing these comments. We look forward to receiving the NCI's response.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

James Love. Knowledge Ecology International

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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**From:** Lubet, Martha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C84E98D4E0B484B8D44307C97D26597-LUBETM]  
**Sent:** 8/24/2020 4:45:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: KEI comments on Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)

Hi Mark,  
I sent letter to KEI and received the response below.

The prospective licensee is [b4,b5] company.  
Can you provide some advice on how to respond.

Martha

Martha Lubet Ph.D.  
Technology Transfer Manager  
Technology Transfer Center NCI/ NIH  
Phone: 240 276-5508  
FAX: 240 276-5504  
email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)  
<http://ttc.nci.nih.gov>

Mailing Address:  
NCI Technology Transfer Center  
9609 Medical Center Drive Office 1E448 Mail Stop 9702  
Rockville, MD 20850

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**From:** James Love <james.love@keionline.org>  
**Sent:** Monday, August 24, 2020 12:25 PM  
**To:** Lubet, Martha (NIH/NCI) [E] <lubetm@mail.nih.gov>  
**Cc:** Claire Cassedy <claire.cassedy@keionline.org>  
**Subject:** Re: KEI comments on Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)

What is the answer to the question about US manufacturing?

On Mon, Aug 24, 2020 at 10:55 AM Lubet, Martha (NIH/NCI) [E] <lubetm@mail.nih.gov> wrote:

The response to your email of August 20,2020 is attached.

Best regards,

Martha

REL0000024989



Martha Lubet Ph.D.  
Technology Transfer Manager  
Technology Transfer Center NCI/ NIH  
Phone: 240 276-5508  
FAX: 240 276-5504  
email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)  
<http://ttc.nci.nih.gov>

Mailing Address:

NCI Technology Transfer Center  
9609 Medical Center Drive Office 1E448 Mail Stop 9702  
Rockville, MD 20850

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**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Sent:** Thursday, August 20, 2020 3:52 PM

**To:** Lubet, Martha (NIH/NCI) [E] <[lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)>

**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

**Subject:** KEI comments on Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)

Martha T. Lubet, Ph.D.  
Licensing and Patenting Manager  
NCI Technology Transfer Center  
Email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)

--

James Love. Knowledge Ecology International

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<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

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<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AaffA5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/16/2019 3:49:50 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]  
**Subject:** KEI Response\_UR.docx  
**Attachments:** KEI Response\_UR.docx

Hello Guys,

Please review the attached before I send it to KEI.

Thanks,

Uri



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
Uri Reichman, Ph.D., MBA  
[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)

**b5**

---

**From:** kathryn ardizzone [kathrynardizzonekei@gmail.com]  
**Sent:** 12/4/2019 8:41:15 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Bayha, Ryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d5a4353cd514322a8598dbb1751ee79-bayhar]  
**Subject:** Re: Letter from NIH dated November 26, 2019

Hi Mark,

Confirmed.

Thank you,  
Kathryn Ardizzone

On Wed, Dec 4, 2019 at 12:05 PM Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)> wrote:

Ms. Ardizzone:

Could you please confirm whether or not you received a letter from me to KEI dated November 26, 2019, which was sent to you by email on November 27, 2019.

Regards,

Mark L. Rohrbaugh, Ph.D., J.D.

Special Advisor for Technology Transfer

Office of Science Policy

National Institutes of Health

--

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009

REL0000024992

kathryn.ardizzone@keionline.org  
(202) 332-2670

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**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 8/21/2020 8:22:22 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries  
**Attachments:** Love, J 200821.pdf

FYI

**From:** James Love <james.love@keionline.org>  
**Sent:** Friday, August 21, 2020 4:13 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] <afauci@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] <jharper@niaid.nih.gov>  
**Subject:** Re: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

What does this mean as regard the narrow issue raised in the letter, namely the geographic scope of exclusivity for a treatment for an HIV invention? Does this mean that NIAID will go exclusive in South Africa, Brazil and India, or non-exclusive? Some plain talk here is needed, given the extensive interest in this issue, including by patient groups in South Africa and elsewhere.

Jamie

On Fri, Aug 21, 2020 at 4:00 PM Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:

Dear Mr. Love,

On behalf of Dr. Anthony Fauci and the National Institute of Allergy and Infectious Diseases, I thank you for your letter dated July 30, 2020. Dr. Fauci requested that I respond.

My response is attached.

Sincerely,

**Michael R. Mowatt, Ph.D.**

Director, Technology Transfer and Intellectual Property Office

**National Institute of Allergy and Infectious Diseases**

REL0000024994

National Institutes of Health

U.S. Department of Health and Human Services

+1 301 496 2644



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**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Sent:** Thursday, July 30, 2020 11:59 AM

**To:** Fauci, Anthony (NIH/NIAID) [E] <[AFAUCI@niaid.nih.gov](mailto:AFAUCI@niaid.nih.gov)>

**Cc:** Paul Davis <[pdavisx@gmail.com](mailto:pdavisx@gmail.com)>; Sawyer, Eric <[ERICLSAWYER@gmail.com](mailto:ERICLSAWYER@gmail.com)>; Brook Baker <[b.baker@northeastern.edu](mailto:b.baker@northeastern.edu)>; Thiru Balasubramaniam <[thiru@keionline.org](mailto:thiru@keionline.org)>; Morten, Christopher <[christopher.morten@nyu.edu](mailto:christopher.morten@nyu.edu)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Peter Maybarduk <[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)>; lumbasia@citizen.org; Luis Villalon <[info@innovarte.cl](mailto:info@innovarte.cl)>; Merith Basey <[merith@essentialmedicine.org](mailto:merith@essentialmedicine.org)>; lpma75@gmail.com; Gopa Kumar <[kumargopakm@gmail.com](mailto:kumargopakm@gmail.com)>; Sangeeta <[sangeeta@twnetwork.org](mailto:sangeeta@twnetwork.org)>; Umunyana Rugege <[rugege@section27.org.za](mailto:rugege@section27.org.za)>; Ngqabutho Mpofu <[ngqabutho.mpofu@mail.tac.org.za](mailto:ngqabutho.mpofu@mail.tac.org.za)>; Manuel MARTIN <[Manuel.MARTIN@geneva.msf.org](mailto:Manuel.MARTIN@geneva.msf.org)>; Yuanqiong HU <[Yuanqiong.HU@geneva.msf.org](mailto:Yuanqiong.HU@geneva.msf.org)>

**Subject:** Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Dr. Fauci,

Attached is a letter from several individuals and groups, asking that NIAID not grant exclusive rights in a HIV patent license for South Africa, India and other low income countries.

The license is to RNAceuticals, a firm without a web page. The technology is for N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains.

REL0000024994

This letter addresses a narrow issue, the geographic scope of the license, and it asks that exclusivity does not extend to countries like South Africa and India, that have per capita incomes less than 30 percent of the United States.

Among the groups signing are the leading patient group for persons living with HIV in South Africa, where an estimated 19 percent of persons from 19 to 49 are living with HIV, and patient advocacy groups working in Southeast Asia, India, Brazil, Chile, Mexico, Ecuador, Argentina, Colombia, and Guatemala, as well as several US and globally based health groups and patient advocates.

Jamie

--

James Love. Knowledge Ecology International

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

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[twitter.com/jamie\\_love](https://twitter.com/jamie_love)





National Institutes of Health  
National Institute of Allergy  
and Infectious Diseases

Technology Transfer and  
Intellectual Property Office

5601 Fishers Lane,  
Suite 6D, MSC 9804  
Rockville, MD. 20852  
(Zip Code for Courier: 20817)  
301-496-2644

VIA ELECTRONIC MAIL

August 21, 2020

Mr. James Love  
Director, Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009

Re: Your letter dated July 30, 2020

Dear Mr. Love,

On behalf of Dr. Anthony Fauci and the National Institute of Allergy and Infectious Diseases (NIAID), I thank you for your letter dated July 30, 2020. Dr. Fauci requested that I respond.

Your letter relates to the Federal Register Notice (FRN) published on July 10, 2020 (85 FR 41607). As you know, 35 USC 209 and 37 CFR part 404 require public notice of an intent to grant an exclusive license to government-owned inventions. The FRN fulfills this requirement.

The National Institutes of Health (NIH), of which NIAID is a part, takes very seriously its responsibilities as a steward of government-owned intellectual property. In this context we appreciate your comments, noting that they align with longstanding policy and practice at the NIH, which prioritizes the licensing of these rights in a manner that maximizes the development, commercialization, and public use of biomedical innovations to benefit not only persons in the United States, but also around the world.

Sincerely,

Michael R.  
Mowatt -S

Digitally signed by Michael  
R. Mowatt -S  
Date: 2020.08.21 11:30:25  
-04'00'

Michael R. Mowatt, Ph.D.  
Director, Technology Transfer and Intellectual Property Office

cc: A Fauci  
J Harper

---

**From:** kathryn ardizzone [kathrynardizzonekei@gmail.com]  
**Sent:** 12/4/2019 5:05:39 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Out of Office Re: Letter from NIH dated November 26, 2019

I am out of the office on leave but will be checking email periodically and will answer as quickly as possible. If you need immediate assistance, please contact my colleague, Claire Cassedy, at [claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org).

Thank you.

--  
Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Girards, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F43C30C4A364463BF5B2C134225B7F0-GIRARDSRT]  
**Sent:** 7/7/2020 11:34:12 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; McGuinness, Charlotte (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=920f87916f8441f387c5ab78e5081191-mcguinnnc]  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

OK- thanks again- I will proceed as you suggest.

While I will certainly respond as you have suggested,

b5

b5

Hence, my suggestion that

b5

b5

b5

When you stated

b5

b5

it sounded to me as if

b5

b5

And I did receive some

b5

As such, might it be of value to

b5

b5

-Rick

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

**Sent:** Monday, July 6, 2020 5:17 PM

**To:** Girards, Richard (NIH/NCI) [E] <richard.girards@nih.gov>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>

**Subject:** Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

See my edits.

b5

b5

Sent from my iPhone

On Jul 6, 2020, at 3:43 PM, Girards, Richard (NIH/NCI) [E] <richard.girards@nih.gov> wrote:

Got it- thanks!

Are the revised versions immediately below more acceptable?

REL0000024999

1. What is the development stage of the invention?

**b5**

2. What grant numbers are associated with the inventions?

**b5**

3. How much did the NIH spend to develop the inventions?

**b5**

4. Are there any clinical trials of the inventions? If so, what are they

**b5**

5. How did NIH determine that exclusivity is a reasonable and necessary incentive?

**b5**

6. How did NIH determine that the scope of the license is not broader than necessary?

**b5**

7. What is the period of exclusivity?

**b5**

8. Have/will NIH consider a period of exclusivity shorter than life of patent?

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Sent:** Monday, July 6, 2020 3:13 PM

**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>

**Subject:** Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Rick:

REL0000024999

b5

If you have questions, let's chat.  
Please send me the proposed final.  
Thanks  
Mark  
Sent from my iPhone

On Jul 6, 2020, at 3:04 PM, Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)> wrote:

Dear Mark-

Do you have any comments, in addition to Misha's comments?

Thanks again.

-Rick

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Sent:** Monday, July 6, 2020 2:38 PM  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>; McGuinness, Charlotte (NIH/NCI) [E] <[mcguinncc@mail.nih.gov](mailto:mcguinncc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Also, please run this by Mark.

**From:** Shmilovich, Michael (NIH/NHLBI) [E]  
**Sent:** Monday, July 6, 2020 14:37  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>; McGuinness, Charlotte (NIH/NCI) [E] <[mcguinncc@mail.nih.gov](mailto:mcguinncc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Rick – this looks fine to me with regards to item 7,

b5

b5

**From:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>

**Sent:** Monday, July 6, 2020 14:33

**To:** McGuinness, Charlotte (NIH/NCI) [E] <[mcguinncc@mail.nih.gov](mailto:mcguinncc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>; Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>

**Subject:** FW: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Dear all:

With respect to the attached Notice, I received the following list of questions from KEI.

My proposed responses are in red. Please do let me know if you have any thoughts-thanks.

1. What is the development stage of the invention?

**b5**

2. What grant numbers are associated with the inventions?

**b5**

3. How much did the NIH spend to develop the inventions?

**b5**

4. Are there any clinical trials of the inventions? If so, what are their numbers?

**b5**

5. How did NIH determine that exclusivity is a reasonable and necessary incentive?

**b5**

6. How did NIH determine that the scope of the license is not broader than necessary?

**b5**

7. What is the period of exclusivity?

**b5**

8. Have/will NIH consider a period of exclusivity shorter than life of patent?

**b5**

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Monday, July 6, 2020 1:55 PM

**To:** Girards, Richard (NIH/NCI) [E] <richard.girards@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Dear Mr. Girards:

As soon as practicable, please answer the following questions regarding the license described above.

1. What is the development stage of the invention?
2. What grant numbers are associated with the inventions?
3. How much did the NIH spend to develop the inventions?
4. Are there any clinical trials of the inventions? If so, what are their numbers?
5. How did NIH determine that exclusivity is a reasonable and necessary incentive?
6. How did NIH determine that the scope of the license is not broader than necessary?
7. What is the period of exclusivity?
8. Have/will NIH consider a period of exclusivity shorter than life of patent?

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

<2020-13316.pdf>

**From:** Lubet, Martha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C84E98D4E0B484B8D44307C97D26597-LUBETM]  
**Sent:** 8/21/2020 5:43:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**CC:** Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]  
**Subject:** RE: KEI email in response to Federal Register notice for license app A-287-2020 ( Precithera)  
**Attachments:** Letter to KEI.docx

Mark,  
Thanks for advice.  
Attach is a draft of letter to KEI. Please review.

Can the letter be sent via email or do I need to send it via snail mail?

Martha

Martha Lubet Ph.D.  
Technology Transfer Manager  
Technology Transfer Center NCI/ NIH  
Phone: 240 276-5508  
FAX: 240 276-5504  
email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)  
<http://ttc.nci.nih.gov>

Mailing Address:  
CSC c/o NCI Technology Transfer Center  
9609 Medical Center Drive Office 1E448 Mail Stop 9702  
Rockville, MD 20850

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, August 21, 2020 12:00 PM  
**To:** Lubet, Martha (NIH/NCI) [E] <[lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Cc:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Subject:** RE: KEI email in response to Federal Register notice for license app A-287-2020 ( Precithera)

Martha:

Thanks for letting me know.

b5

b5

b5

Happy to review a draft.

Regards,  
Mark

**From:** Lubet, Martha (NIH/NCI) [E] <[lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)>  
**Sent:** Friday, August 21, 2020 11:08 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

REL0000025000



**Cc:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Subject:** KEI email in response to Federal Register notice for license app A-287-2020 ( Precithera)

Hi Mark,

I received a response from KEI for the Federal Register notice for the exclusive license to Precithera.

I also received an email from James Love asking for the status of the stage of development for the technology (E-003-2014).

I checked with Richard Rodriguez. He indicated that I should work with you on the response to KEI.

Attached to this email are the emails from KEI, the Federal Register notice and the signed PD.

Thanks,

Martha

Martha Lubet Ph.D.  
Technology Transfer Manager  
Technology Transfer Center NCI/ NIH  
Phone: 240 276-5508  
FAX: 240 276-5504  
email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)  
<http://ttc.nci.nih.gov>

Mailing Address:  
CSC c/o NCI Technology Transfer Center  
9609 Medical Center Drive Office 1E448 Mail Stop 9702  
Rockville, MD 20850

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REL0000025000



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI  
9609 Medical Center Drive, Suite 530  
Rockville, MD 20852  
Office (240) 276-5530  
Facsimile (240) 276-5504

**b5**

---

**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 10/15/2019 6:48:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer 84 FR 52890

Hi Mark,

Please see below for draft responses to the most recent set of KEI questions.

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, October 11, 2019 10:50 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer 84 FR 52890

Dear Dr. Burke,

KEI is researching the prospective NIH exclusive patent license, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, described at 84 FR 52890.

The license notice pertains to two inventions, E-029-2019, and E-135-2019. For ease of reference, we will refer to the first invention as "Invention A" and the second invention as "Invention B."

At your earliest convenience, please answer the following questions regarding the licenses:

At what stage of research and development is Invention A? Invention B? b5  
b5

Is Invention A being investigated in any clinical trials? If so, can you please provide their numbers? What about Invention B? b5

How much has the NIH spent to support the development of Invention A? What about Invention B? b5  
b5

Is the period of exclusivity to be life of patent or less than life of patent? b5  
b5

If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

If not, have you considered whether the license will tend to substantially lessen competition?

The fields of use (treatment of human cancers, companion diagnostics) can be fairly characterized as broad. Why are they so expansive? b5

**b5**

On what basis did the NIH conclude that an exclusive (as opposed to non-exclusive or partially exclusive) license to Ziopharm was a necessary incentive under 35 U.S.C. § 209(a)(1)? **b5**

**b5**

(The NIH OTT Website states that non-exclusive licenses are preferred, and that the NIH Technology Transfer officer determines that exclusivity is appropriate before publishing notice of the prospective license and inviting public comment.)

How has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary?

What criteria was used to select Ziopharm selected as licensee?

**b5**

**b5**

How does this proposed license relate to previous licenses to Ziopharm? There seems to be an overlap in the technology. **b5**

Please provide a list of other firms that expressed an interest in this license:

**b5**

**b5**

Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

---

**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 12/4/2019 5:06:31 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** RE:

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, December 4, 2019 12:06 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE:

I suggest b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Wednesday, December 4, 2019 12:04 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE:

When we discussed it between the three of us we decided that

b5

b5

Moreover, b5

b5

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Wednesday, December 4, 2019 12:01 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:**

b5

---

**From:** Girards, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F43C30C4A364463BF5B2C134225B7F0-GIRARDSRT]  
**Sent:** 7/6/2020 7:43:54 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Got it- thanks!

Are the revised versions immediately below more acceptable?

1. What is the development stage of the invention?

b5

2. What grant numbers are associated with the inventions?

b5

3. How much did the NIH spend to develop the inventions?

b5

4. Are there any clinical trials of the inventions? If so, what are their numbers?

b5

5. How did NIH determine that exclusivity is a reasonable and necessary incentive?

b5

6. How did NIH determine that the scope of the license is not broader than necessary?

b5

7. What is the period of exclusivity?

b5

8. Have/will NIH consider a period of exclusivity shorter than life of patent?

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, July 6, 2020 3:13 PM  
**To:** Girards, Richard (NIH/NCI) [E] <richard.girards@nih.gov>

**Subject:** Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Rick:

b5

If you have questions, let's chat.  
Please send me the proposed final.  
Thanks  
Mark  
Sent from my iPhone

On Jul 6, 2020, at 3:04 PM, Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)> wrote:

Dear Mark-

Do you have any comments, in addition to Misha's comments?

Thanks again.

-Rick

---

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Sent:** Monday, July 6, 2020 2:38 PM  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>; McGuinness, Charlotte (NIH/NCI) [E] <[mcguinnnc@mail.nih.gov](mailto:mcguinnnc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Also, please run this by Mark.

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**From:** Shmilovich, Michael (NIH/NHLBI) [E]  
**Sent:** Monday, July 6, 2020 14:37  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>; McGuinness, Charlotte (NIH/NCI) [E] <[mcguinnnc@mail.nih.gov](mailto:mcguinnnc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Rick – this looks fine to me with regards to item 7,

b5

b5

**From:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>

**Sent:** Monday, July 6, 2020 14:33

**To:** McGuinness, Charlotte (NIH/NCI) [E] <[mcguinncc@mail.nih.gov](mailto:mcguinncc@mail.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>; Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>

**Subject:** FW: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

Dear all:

With respect to the attached Notice, I received the following list of questions from KEI.

My proposed responses are in red. Please do let me know if you have any thoughts- thanks.

1. What is the development stage of the invention?

b5

2. What grant numbers are associated with the inventions?

b5

3. How much did the NIH spend to develop the inventions?

b5

4. Are there any clinical trials of the inventions? If so, what are their numbers?

b5

5. How did NIH determine that exclusivity is a reasonable and necessary incentive?

b5

6. How did NIH determine that the scope of the license is not broader than necessary?

b5

7. What is the period of exclusivity?

b5

8. Have/will NIH consider a period of exclusivity shorter than life of patent?

b5

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Monday, July 6, 2020 1:55 PM

**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer



Dear Mr. Girards:

As soon as practicable, please answer the following questions regarding the license described above.

1. What is the development stage of the invention?
2. What grant numbers are associated with the inventions?
3. How much did the NIH spend to develop the inventions?
4. Are there any clinical trials of the inventions? If so, what are their numbers?
5. How did NIH determine that exclusivity is a reasonable and necessary incentive?
6. How did NIH determine that the scope of the license is not broader than necessary?
7. What is the period of exclusivity?
8. Have/will NIH consider a period of exclusivity shorter than life of patent?

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670  
<2020-13316.pdf>

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**From:** Lubet, Martha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C84E98D4E0B484B8D44307C97D26597-LUBETM]  
**Sent:** 8/21/2020 3:08:16 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrir]  
**CC:** Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]  
**Subject:** KEI email in response to Federal Register notice for license app A-287-2020 ( Precithera)  
**Attachments:** Potential SPAM:KEI comments on Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394); Potential SPAM:For Martha T. Lubet, Ph.D.,; A-287-2020\_Fed. Reg notice.pdf; 07\_27\_2020 PD A-287-2020 signed.pdf

Hi Mark,

I received a response from KEI for the Federal Register notice for the exclusive license to Precithera.

I also received an email from James Love asking for the status of the stage of development for the technology (E-003-2014).

I checked with Richard Rodriguez. He indicated that I should work with you on the response to KEI.

Attached to this email are the emails from KEI, the Federal Register notice and the signed PD.

Thanks,

Martha

Martha Lubet Ph.D.  
Technology Transfer Manager  
Technology Transfer Center NCI/ NIH  
Phone: 240 276-5508  
FAX: 240 276-5504  
email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)  
<http://ttc.nci.nih.gov>

Mailing Address:  
CSC c/o NCI Technology Transfer Center  
9609 Medical Center Drive Office 1E448 Mail Stop 9702  
Rockville, MD 20850

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REL0000025005

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**From:** James Love [james.love@keionline.org]  
**Sent:** 8/20/2020 7:51:36 PM  
**To:** Lubet, Martha (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c84e98d4e0b484b8d44307c97d26597-lubetm]  
**CC:** Claire Cassedy [claire.cassedy@keionline.org]  
**Subject:** Potential SPAM:KEI comments on Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)  
**Attachments:** PreciTheralicense-KEI-20aug2020.pdf

Martha T. Lubet, Ph.D.  
Licensing and Patenting Manager  
NCI Technology Transfer Center  
Email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov)

--

James Love. Knowledge Ecology International  
U.S. Mobile +1.202.361.3040  
U.S. office phone +1.202.332.2670  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

20 August 2020

Martha T. Lubet, Ph.D.  
Licensing and Patenting Manager  
NCI Technology Transfer Center  
Email: lubetm@mail.nih.gov

**Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)**

Dear Dr. Lubet,

KEI offers the following comments on the "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia" to PreciThera, Inc, located in Montreal, Canada.

**PreciThera, Inc.**

The company is not based in the United States, making it even more compelling for the NIH to protect U.S. residents from paying prices greater than other high income countries.

The key staff and board members appear to be well qualified in terms of science and finance.

This is technology financed by U.S. taxpayers, and the company to receive the license is foreign owned and operated. The terms of any license should reflect the obligation, in 35 U.S.C. 209, to limit exclusivity to that which is necessary, and in 35 U.S.C. 201(f), to ensure that inventions are made "available to the public on reasonable terms."

How will the NIH address and enforce the Bayh-Dole U.S. manufacturing requirement in the case of this license?

**The 35 U.S.C. 209 analysis**

35 U.S.C. 209 has several restrictions on the grant of an exclusive license. In 209(a)(1), the agency has to determine if exclusivity is a reasonable and necessary incentive to induce the investments to bring an invention to practical application.

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public;

Additionally, if some exclusivity is warranted, the agency still has to determine the scope of exclusivity, and is required to ensure that that the proposed scope of exclusivity is not greater than reasonably necessary:

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

...

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

No exclusive license should be granted until the NIH conducts some type of economic analysis to determine if exclusivity can be limited to less than the life of the patent, as was the case, for example, for all extramural funded patents when the Bayh-Dole Act was passed in 1980, and under previous NIH Directors, as in the case of the ddl license, for an HIV drug.

Videx® Expanding Possibilities: A Case Study, National Institutes of Health Office of Technology Transfer, September 2003.

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf>

"The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could become non-exclusive early, prior to the expiration of the NIH patents. Several companies competed for the license."

Any exclusive license should limit the number of years of exclusivity to that which is "reasonably necessary to provide the incentive for bringing the invention to practical application," and this requires an evaluation of the risks and costs of trials and other R&D necessary to advance a product to regulatory approval, as well as the potential market for a product upon such approval.

### **Limits on the term of exclusivity**

We ask that the NIH narrow the scope of exclusivity by using sales targets to trigger shorter terms, such as by reducing exclusivity for one year for every half billion dollars in sales after the first billion dollars of sales.

### **Limit on US exclusivity**

We ask that if exclusive rights are granted, that this only be in high income countries, but not in the United States. Or at a minimum, have the U.S. exclusivity shorter than the exclusivity in other high income countries, perhaps after global revenue targets are reached.

### **40 U.S.C. § 559 - Advice of Attorney General with respect to antitrust law**

We insist that the NIH seek the advice of the U.S. Attorney General, as is required by 40 U.S.C. § 559(b)(1).

### **Additional issues if an exclusive license is granted**

We request that the NIH includes the following additional provisions to protect the public's interest in NIH-funded technology:

**Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

**Low and middle income countries.** The exclusive licenses should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in countries with significantly lower incomes.

**Global registration and affordability.** The licenses should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

**Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

**Transparency of R&D outlays.** The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

#### **Acknowledgement of federal funding - publication and publicity**

The licensee should be required to clearly state, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and federal funding of the research and development.

#### **Additional transparency issues**

The license should have provisions that give effect to the transparency norms set out in WHA72.8 “Improving the transparency of markets for medicines, vaccines, and other health products”, a resolution enthusiastically supported by HHS last year.

Please notify us if a license is actually granted, so we can request a copy under the FOIA.

Sincerely,

James Love, on behalf of Knowledge Ecology International  
james.love@keionline.org

---

**From:** James Love [james.love@keionline.org]  
**Sent:** 8/20/2020 4:58:10 PM  
**To:** Lubet, Martha (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c84e98d4e0b484b8d44307c97d26597-lubetm]  
**Subject:** Potential SPAM:For Martha T. Lubet, Ph.D.,

Martha T. Lubet, Ph.D.

Can you tell me the stage of development for this tech?

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia to: PreciThera, Inc, located in Montreal, Canada. (85 FR 47394)

Jamie

--

James Love. Knowledge Ecology International  
U.S. Mobile +1.202.361.3040  
U.S. office phone +1.202.332.2670  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)



applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Biomedical Informatics, Library and Data Sciences Review Committee.

*Date:* November 5, 2020.

*Time:* 9:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Virtual meeting.

*Contact Person:* Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892-7968, 301-594-4937, [huangz@mail.nih.gov](mailto:huangz@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: July 30, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-17024 Filed 8-4-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to PreciThera, Inc. located in Montreal, Canada.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before August 20, 2020 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Martha T. Lubet, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, Telephone:

(240) 276-5530 or Email: [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Intellectual Property

(United States Provisional) Patent Application No. 61/927904, filed January 15, 2014 and entitled: "Cartilage Targeting Agents and Their Use" [HHS Reference No. E-003-2014/0-US-01]; (PCT) Patent Application PCT/US2015/011433, filed January 14, 2015 and entitled "Cartilage Targeting Agents and Their Use" [HHS Reference No. E-003-2014/0-PCT-02]; (and U.S. and foreign patent applications claiming priority to the aforementioned applications).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

(A) A fusion protein comprising one of the anti-matrilin 3 binding agents and insulin-like growth factor 1 (IGF-1) for the treatment of short stature of humans with primary IGF-1 deficiency and

(B) a fusion protein comprising one of anti-matrilin 3 binding agents and C-type natriuretic protein for the treatment of humans with achondroplasia.

This technology discloses antigen binding antibody fragments that bind to matrilin-3. These agents were selected from a yeast display antibody library for the ability to bind to human or mouse matrilin-3. Matrilin-3 is strongly expressed in the epiphyseal growth plate of bones. In some embodiments, the antibody fragments are linked to an effector molecule (e.g. growth hormone, IGF-1, or C-type natriuretic protein). Methods of using the anti-Matrilin-3 binding agents to treat skeletal dysplasia, short stature and osteoarthritis are also disclosed.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development receive written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license

application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 28, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020-17098 Filed 8-4-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6195-N-02]

#### Mortgage and Loan Insurance Programs Under the National Housing Act—Debenture Interest Rates

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Administration under the provisions of the National Housing Act (the Act). The interest rate for debentures issued under Section 221(g)(4) of the Act during the 6-month period beginning July 1, 2020, is  $\frac{5}{8}$  percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the 6-month period beginning July 1, 2020, is  $1\frac{1}{4}$  percent.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Olazabal, Department of Housing and Urban Development, 451 Seventh Street SW, Room 5146, Washington, DC 20410-8000; telephone (202) 402-4608 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

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**b4,b5**

**b4,b5**



**b4,b5**

**b4,b5**

**From:** Fenn, Tedd (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B0F88C66575C49FB9F70456838521059-FENNEA]  
**Sent:** 10/15/2019 6:32:21 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** FW: Questions re: Prospective Grant of an Exclusive Patent License, 84 FR 52889

Hi Mark,  
I've attached below my proposed responses to questions from KEI, please advise.  
-Thank you,  
Tedd

<p>Question: Are you negotiating one license over six different licenses, or are you negotiating six different licenses, one for each invention?</p>	<div data-bbox="492 741 1052 787">b5</div>
<p>Question: At what stage of research and development is each invention?</p>	<div data-bbox="857 1371 1060 1518">b5</div>
<p>Question: Please state whether each invention can be considered a research tool.</p>	

Question: On what basis did the NIH conclude that an exclusive license was necessary to commercialize the subject invention?

Question: For each invention, please state whether it has been investigated in any clinical trial (Yes or No). If your answer is "Yes," please provide the NCT Clinical Trial Nos.

Question: What is the duration of the license(s)?

Question: Why did you select Opsis Therapeutics, LLC as licensee?

Question: How does the field of use listed in the Notice satisfy the Chapter No. 300, PHS Licensing Policy to ensure that a licensee

**b5**

obtains the appropriate scope of rights necessary to develop a potential application of the invention. This enables as many companies as possible to obtain commercial development rights, resulting in the concurrent development of many potential applications and the further promotion of the invention's utilization by the public.

Question: Please provide a list of other companies that applied to license any of the above-listed inventions.

Question: Has the NIH sought the antitrust advice of the U.S. Attorney General in relation to the license(s)?

Question: How has NIH ensured that the license(s) will not tend to substantially lessen competition?

b5

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Friday, October 11, 2019 12:10 PM

**To:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>

**Subject:** Questions re: Prospective Grant of an Exclusive Patent License, 84 FR 52889

Dear Mr. Fenn:

At your earliest convenience, please answer the following questions regarding the prospective exclusive patent license to Opsi Therapeutics, LLC, described at 84 FR 52889. KEI is researching this prospective license, in exercising its right to public comment under Section 209(e) of the Bayh-Dole Act.

Question: Are you negotiating one license over six different licenses, or are you negotiating six different licenses, one for each invention?

Question: At what stage of research and development is each invention?

Question: Please state whether each invention can be considered a research tool.

Question: On what basis did the NIH conclude that an exclusive license was necessary to commercialize the subject invention?

**b5**

Question: For each invention, please state whether it has been investigated in any clinical trial (Yes or No). If your answer is "Yes," please provide the NCT Clinical Trial Nos.

Question: What is the duration of the license(s)?

Question: Why did you select Opsi Therapeutics, LLC as licensee?

Question: How does the field of use listed in the Notice satisfy the Chapter No. 300, PHS Licensing Policy to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the invention. This enables as many companies as possible to obtain commercial development rights, resulting in the concurrent development of many potential applications and the further promotion of the invention's utilization by the public.

Question: Please provide a list of other companies that applied to license any of the above-listed inventions.

Question: Has the NIH sought the antitrust advice of the U.S. Attorney General in relation to the license(s)?

Question: How has NIH ensured that the license(s) will not tend to substantially lessen competition?

**b5**

Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



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**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/24/2020 7:20:31 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrig]  
**Subject:** RE: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2  
**Attachments:** Joint Comments, Exclusive Patent License, Anti-GPC2 CAR Therapy to Stanford University.pdf

Hi Mark,

Please see below for my draft for a response to KEI. Let me know any suggestions, changes, etc. I'm re-attaching their comments here in case you need them.

Thanks!  
Rose

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Dear Ms. Ardizzone,

**b5**

Best Regards,  
Rose Freel

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
National Cancer Institute  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

REL0000025007

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, February 19, 2020 5:54 PM  
**To:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

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b5	You might add
b5	You can conclude with
b5	
b5	

Please send the draft back for review.  
Than sk

**From:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>  
**Sent:** Wednesday, February 19, 2020 5:41 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Dale and Mark,

Just following up since I got Dale's out of office last week. Let me know what you think or if you'd like to discuss.

Best,  
Rose

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Wednesday, February 12, 2020 9:30 AM  
**To:** Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** FW: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Dale and Mark,

I've received formal comments from KEI on the intent to grant notice for the IIA with Stanford. I've reviewed their comments and much of it is either repetitive to what they've already emailed me or the same comments they've made on previous intent to grant notices. How would you advise I respond to these comments?

Thanks!  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Monday, February 10, 2020 6:20 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; manon.ress@cancerunion.org; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>  
**Subject:** Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Dr. Freel:

Attached, please find the joint comments of Knowledge Ecology International, Union for Affordable Cancer Treatment, and Manon Ress, with respect to the "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2."

Thank you in advance for reviewing these comments. We look forward to receiving the NCI's response.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

REL0000025007



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

February 10, 2020

Rose M. Freel, Ph.D.  
Senior Licensing and Patenting Manager  
NCI Technology Transfer Center  
8490 Progress Drive, Suite 400  
Frederick MD 21701  
Via Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**Re: "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2" to Stanford University**

Dear Dr. Freel:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), and Manon Ress are writing to comment on the "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2," to Stanford University, 85 Federal Register 4332 (hereinafter, "the Federal Register notice" or "the 85 FR 4332 notice").<sup>1</sup>

The subject invention involves a CAR T-cell therapy targeting the Glypican-2 cell surface protein, which is expressed in at least 38 forms of cancer, including neuroblastoma, glioblastoma, breast cancer, lung cancer, lymphoma, and leukemia.<sup>2</sup>

Stanford, the United States, and Children's Hospital of Philadelphia (CHOP) co-own the technology. According to the NIH, the purpose of the license is to enable Stanford to sublicense the invention to a commercial partner.

In 2019, Stanford received over half a billion dollars in National Institutes of Health (NIH) research grants<sup>3</sup> and \$49.3 million in licensing revenue,<sup>4</sup> while the National Institutes of Health (NIH) received only \$78.2 million in royalties for all of its patent licenses combined.<sup>5</sup>

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<https://www.federalregister.gov/documents/2020/01/24/2020-01154/prospective-grant-of-exclusive-patent-license-antibody-based-therapeutics-and-chimeric-antigen>.

<sup>2</sup> <https://portals.broadinstitute.org/ccle/page?gene=GPC2>.

<sup>3</sup> [https://projectreporter.nih.gov/reporter\\_ChartResults.cfm?icde=48703011](https://projectreporter.nih.gov/reporter_ChartResults.cfm?icde=48703011).

<sup>4</sup> <https://otl.stanford.edu/about/about-us/fast-facts>.

<sup>5</sup> <https://www.ott.nih.gov/reportsstats/ott-statistics>.

If granted, the license should provide the U.S. a commensurate share of Stanford's sublicense royalty payments, to reward taxpayers' contribution to the technology.

The NIH's failure to answer KEI's questions regarding this license has impeded our ability to participate in the notice-and-comment process, which is protected by 35 U.S.C. § 209(e). The little that the NIH would say about the license demonstrates that it has not applied the criteria under 35 U.S.C. § 209(a)(1)-(2). Finally, the NIH must consult the antitrust advice of the U.S. Attorney General before executing the license.

In the event that the NIH grants the license, it should incorporate provisions designed to safeguard the public interest and promote the policy objectives of the Bayh-Dole Act and the Public Health Service (PHS) Technology Transfer Policy Manual.

## Background

### The Invention

The prospective license involves an invention titled "Chimeric Antigen Receptors Targeting Glycipan-2 [sic]," United States Provisional Patent Application No. 62/844,695 filed May 7, 2019.

The prospective license includes "all continuing U.S. and foreign patents/patent applications thereof."<sup>6</sup>

Glypican-2 or GPC2 is a cell surface protein that is highly expressed in many human cancers, but not in healthy tissues, making it a target for cancer immunotherapy.<sup>7</sup>

The invention was jointly developed and is co-owned by the United States, Stanford University, and CHOP.

According to the Federal Register notice, the purpose of this license is to enable Stanford to sublicense the invention to a commercial partner. Unlike other NIH patent license notices, the 85 FR 4332 notice specifies that this license is an "exclusive, sublicensable patent license[]" and that the license "will be sublicensable["]<sup>8</sup>

Since August of 2019, Stanford's Office of Technology Licensing has published a license notice titled "Chimeric Antigen Receptors Targeting Glycipan-2," Docket No. S18-453 ("the Stanford notice" or "S18-453").<sup>9</sup>

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<sup>6</sup>

<https://www.federalregister.gov/documents/2020/01/24/2020-01154/prospective-grant-of-exclusive-patent-license-antibody-based-therapeutics-and-chimeric-antigen>.

<sup>7</sup> <https://www.frontiersin.org/articles/10.3389/fimmu.2018.02380/full>.

<sup>8</sup>

<https://www.federalregister.gov/documents/2020/01/24/2020-01154/prospective-grant-of-exclusive-patent-license-antibody-based-therapeutics-and-chimeric-antigen> (emphasis added).

<sup>9</sup> [http://techfinder.stanford.edu/technologies/S18-453\\_chimeric-antigen-receptors](http://techfinder.stanford.edu/technologies/S18-453_chimeric-antigen-receptors).

The Stanford notice and the Federal Register notice appear to describe the same invention.<sup>10</sup> Both notices use the same title to describe the invention, “Chimeric Antigen Receptors Targeting Glycipan-2,” with an identical typographical error—“glypican” spelled as “glycipan.” They also use the same language when describing the invention. Both notices state, verbatim, that GPC2 has “very restricted expression in normal tissue” but expression “on many hard-to-treat pediatric and adult solid tumors,” including “glioblastoma, small cell lung cancer, uterine carcinoma, neuroblastoma, and medulloblastoma.”

The Stanford notice lists the following inventors: Robbie Majzner, Crystal Mackall, Sabine Heitzeneder, John Maris, Kristopher Bosse, Dimiter Dimitrov, and Zhongyu Zhu, but it does not list the inventors’ affiliations. The notice does not mention the role of NCI or CHOP in developing the invention, stating only that “[r]esearchers at Stanford have developed chimeric antigen receptors (CARs) that target glypican-2 (GPC2) and can be used to treat solid tumors.”

<sup>11</sup>

Majzner, Mackall, and Heitzeneder are researchers with Stanford. Maris and Bosse are scientists at CHOP. Dimitrov and Zhu are associated with the National Cancer Institute (NCI).<sup>12</sup> This is consistent with an invention that is co-owned by Stanford, CHOP, and the United States.

### Terms of the License

Once again, the terms of an NIH license to practice a publicly-owned cell therapy are expansive as regards the geographical area, field of use, and the number of years of exclusive rights.

The Federal Register notice does not provide information about the countries in which the NIH plans to file non-provisional patent applications, which limits our understanding of the geographical scope of the proposed license. According to the Federal Register notice, however, the license territory “will be worldwide” and the fields of use “may be limited to those fields of use commensurate in scope with the patent rights[.]”<sup>13</sup> This is, of course, the broadest possible field of use for an exclusive patent license, since a licensor cannot assign patent rights that exceed the scope of rights claimed in the patent.

KEI could not assess the “scope [of] the patent rights” because the provisional patent application is not publicly available.

GPC2 is expressed in at least 38 forms of cancer,<sup>14</sup> according to the Broad Institute of MIT and Harvard Cancer Cell Line Encyclopedia, as shown in Figure 1 below.

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<sup>10</sup> KEI contacted Mona Wan, the contact person for the Stanford notice, and asked her whether United States Provisional Patent Application No. 62/844,695 covered the inventions described in S18-453. She refused to provide this information, and instead suggested that a representative from Stanford’s public relations office will contact KEI.

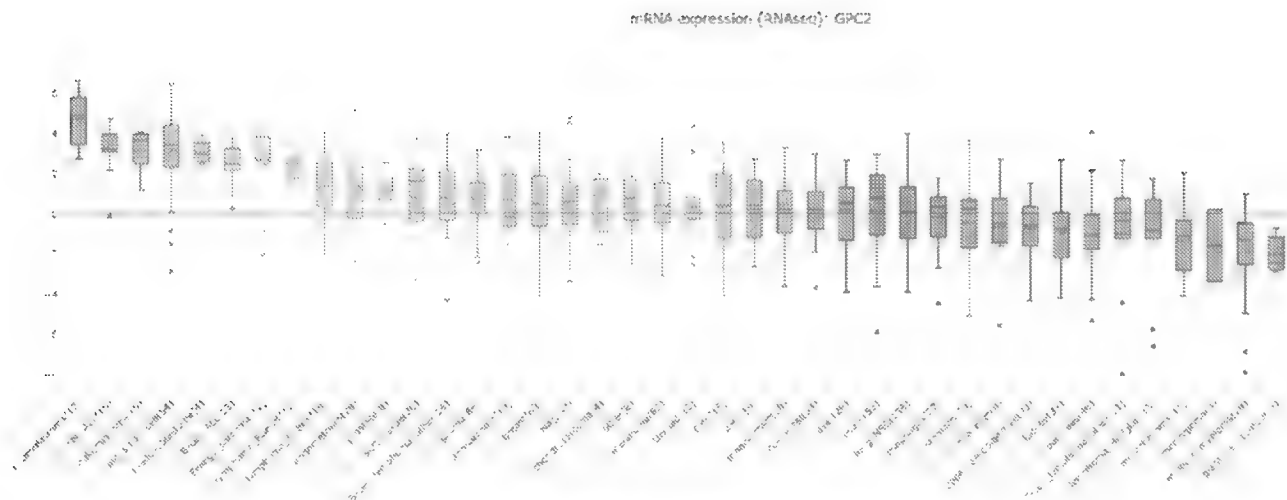
<sup>11</sup> [http://techfinder.stanford.edu/technologies/S18-453\\_chimeric-antigen-receptors](http://techfinder.stanford.edu/technologies/S18-453_chimeric-antigen-receptors).

<sup>12</sup> Dimitrov is retired.

<https://ncifrederick.cancer.gov/about/theposter/content/nci-helps-children%E2%80%99s-hospital-philadelphia-identify-and-treat-new-target-pediatric-cancer>.

<sup>13</sup> [https://docs.google.com/document/d/1vwR3WdVyAwzZ\\_fm5NwJulszTBu\\_yD5rcBhAK9htFF5Y/edit](https://docs.google.com/document/d/1vwR3WdVyAwzZ_fm5NwJulszTBu_yD5rcBhAK9htFF5Y/edit).

<sup>14</sup> <https://portals.broadinstitute.org/ccle/page?gene=GPC2>.



**Figure 1.** Source: <https://portals.broadinstitute.org/ccle/page?gene=GPC2>

The Federal Register notice does not state the proposed duration of the license, and the NIH did not respond to our question about the license term.

#### Prospective Licensee

Under Stanford's technology transfer policies, cash royalties from licenses are paid to the inventors' departments and schools, as well as personal shares for the inventors themselves.<sup>15</sup>

Also, Stanford's licensing policy states that "[t]he period of exclusivity, if any, must be justifiable and in the public interest; an exclusive licensee should not assume that the period of exclusivity is typically the life of the licensed patent."<sup>16</sup>

It is not uncommon for University technology transfer offices to license their inventions to start-up companies formed by the inventor employed with the University. Crystal Mackall, who is listed as one of the inventors of the technology on the Stanford notice, is an owner of and holds equity in Lyell Immunopharma, Inc.,<sup>17</sup> "a cellular therapy company dedicated to mastering immune cell functionality."

<sup>15</sup> <https://otl.stanford.edu/about/about-us>.

<sup>16</sup> [https://otl.sites.stanford.edu/sites/g/files/sbiybj10286/f/streamlining\\_negotiations\\_feb2017.pdf](https://otl.sites.stanford.edu/sites/g/files/sbiybj10286/f/streamlining_negotiations_feb2017.pdf).

<sup>17</sup>

<http://www.med.stanford.edu/news/all-news/2019/01/engineered-immune-cells-target-broad-range-of-pediatric-tumors.html>.

## Discussion

1. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license or that it has ensured that the scope of rights will not be broader than reasonably necessary to induce the investment needed to commercialize the subject technology.

We are concerned that the NIH has not given adequate consideration to whether an exclusive license is necessary for this technology, and, if so, whether the scope of the license is not broader than the incentive necessary to bring the invention to market.

The NIH may not license an invention on an exclusive basis unless, among other conditions:

(1) “granting the license is a reasonable and necessary incentive to – (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public;” and

(2) “the [NIH] finds that the public will be served by the granting of the license ... and that the proposed scope of exclusivity is not greater than reasonably necessary[.]”

35 U.S.C. § 209(a)(1)-(2).

As NIH acknowledged in email to KEI, “[t]he value of patent commercialization licenses are not uniform and depend on many factors[.]” These factors include, but are not limited to:

1. The potential market size/revenues for the invention;
2. The development stage of the technology;
3. The government’s investment in R&D;
4. The costs of financing research and development and bringing the invention to market, including clinical trial costs (and the extent to which those costs may be covered by the Orphan Drug Tax Credit, Research Credit, or reimbursement by health insurance or other subsidies);
5. The existence of regulatory incentives such as test data protection, Orphan Drug exclusivity and the award of one or more priority review vouchers (PRVs).

Below is a discussion of how the relevant factors bear on the invention’s commercial value.

### *Potential Market Size and Revenues*

The potential market size for the invention is expansive, and any product embodying the technology is likely to command high prices.



As noted above, GPC2 is expressed in at least 38 forms of cancer, some of which, like neuroblastoma, are life threatening, lack effective treatments, and affect children.<sup>18</sup>

#### *Research and Development Stage & Cost of Additional R&D Required to Bring Invention to Market*

The development stage of the technology is “preclinical.” The Stanford notice states that the invention has been shown to be “highly effective against GPC2 expressing malignancies in vitro and in vivo in murine xenograph models.”<sup>19</sup>

Co-inventor Kristopher Bosse discusses the development of immunotherapies to cure childhood cancer, including an anti-GPC2 CAR T-cell therapy, in a presentation available at FDA.gov.<sup>20</sup> According to the presentation, Phase 1 clinical trials for CAR T-cells targeting GPC2 are planned for 2020-2021.<sup>21</sup>

Additional R&D costs needed to bring the invention to market may be low compared with the invention’s profitability.

The first two CAR T-cell treatments (Kymriah and Yescarta) were approved by the FDA on the basis of evidence from 63<sup>22</sup> and about 100 patients,<sup>23</sup> respectively. The per-patient costs of such trials were estimated by Professor Carl June, Ph.D, at roughly \$150,000 per patient, making the trial costs trivial (\$10 to \$15 million), relative to revenues, even with adjustments for trial failures

#### *Government Investment in the Technology*

The government has invested millions of dollars toward the invention’s basic and preclinical research.

Based on publicly-available scientific articles mentioning “glypican-2,” KEI has identified three milestones toward the development of the subject invention.

First, GPC2 was identified as an immunotherapy candidate for pediatric cancers by the NCI’s Pediatric Oncology Branch during or before 2012.<sup>24</sup>

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<sup>18</sup> <https://www.childrenwithcancer.org.uk/research/projects/understanding-neuroblastoma/>.

<sup>19</sup> [http://techfinder.stanford.edu/technologies/S18-453\\_chimeric-antigen-receptors](http://techfinder.stanford.edu/technologies/S18-453_chimeric-antigen-receptors).

<sup>20</sup> <https://www.fda.gov/media/129851/download>.

<sup>21</sup> <https://www.fda.gov/media/129851/download>.

<sup>22</sup> <https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states>.

<sup>23</sup>

<https://www.fda.gov/news-events/press-announcements/fda-approves-car-t-cell-therapy-treat-adults-certain-types-large-b-cell-lymphoma>.

<sup>24</sup> Orentas RJ, et al.. “Identification of cell surface proteins as potential immunotherapy targets in 12 pediatric cancers.” *Front Oncol*. 2012;2:194. 2012 Dec 17. doi:10.3389/fonc.2012.00194.

Next, scientists at CHOP “led the research that identified GPC2 as a candidate” for treating neuroblastoma and other high-risk childhood cancers through immunotherapy.<sup>25</sup> This work was supported by at least two NIH grants: T32 CA009615 and T32 GM008638.<sup>26</sup> The NCI scientists developed antibody-drug conjugates targeting GPC2 to support CHOP’s work.<sup>27</sup> The collaboration between CHOP and the NCI resulted in an invention titled, “Glypican 2 as a Cancer Marker and Therapeutic Target,” U.S. Patent Application No. 20180318444 (inventors John Maris, Kristopher Bosse, Dimiter Dimitrov, and Zhongyu Zhu). T32 CA009615 is an NIH grant titled “Cancer Center Research Training Program.” From 2008 through 2017, John Maris, a CHOP scientist who co-invented the technology, was the Principal Investigator for T32 CA009615, and he received millions of dollars for it. T32 GM008638, “Medical Training Research Grant,” has provided University of Pennsylvania/CHOP nearly \$6.3 million. In addition to these grants, NCI has awarded Bosse/CHOP at least \$400,000 for NIH Grant No. K08 CA230223, titled, “Targeting the GPC2 Oncoprotein with Immune-Based Therapies in Neuroblastoma.”

Lastly, NCI scientists “constructed CARs containing anti-GPC2 antibody single domains” and “tested the killing ability of CAR T cells generated from eight individual human donors.”<sup>28</sup> Based on those results, one type of CAR T cells targeting GPC2 was selected for preclinical testing in neuroblastoma models. Half of the mice treated with the CAR T cells were cancer free at the conclusion of the study.<sup>29</sup> The development of CAR T-cells targeting GPC2 was supported by two NIH intramural grants: Z01 BC010891 and ZIA BC010891. For every year of the project since 2014, the total cost for ZIA BC01089, titled “Development of New Antibody-Based Cancer Therapies,” has exceeded one million dollars. Z01 BC010891 is a 2008 grant for \$55,533.

An article co-authored by Stanford co-inventor Robbie Majzner, cites the NCI scientists’ research when discussing the development of a CAR cell therapy targeting GPC2 but does not mention any role performed by the Stanford scientists.<sup>30</sup> KEI asked Dr. Rose Freel, the point of contact for the license, about Stanford’s role in developing the technology, among other questions. She did not answer this question.

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<sup>25</sup>

<https://ncifrederick.cancer.gov/about/theposter/content/nci-helps-children%E2%80%99s-hospital-philadelphia-identify-and-treat-new-target-pediatric-cancer>.

<sup>26</sup> Bosse, Kristopher R et al. “Identification of GPC2 as an Oncoprotein and Candidate Immunotherapeutic Target in High-Risk Neuroblastoma.” *Cancer cell* vol. 32,3 (2017): 295-309.e12.

doi:10.1016/j.ccell.2017.08.003.

<sup>27</sup>

<https://ncifrederick.cancer.gov/about/theposter/content/nci-helps-children%E2%80%99s-hospital-philadelphia-identify-and-treat-new-target-pediatric-cancer>.

<sup>28</sup> Li, Nan et al. “Therapeutically targeting glypican-2 via single-domain antibody-based chimeric antigen receptors and immunotoxins in neuroblastoma.” *Proceedings of the National Academy of Sciences of the United States of America* vol. 114,32 (2017): E6623-E6631. doi:10.1073/pnas.1706055114.

<sup>29</sup> *Id.*

<sup>30</sup> Richards, Rebecca M. et al., “CAR T Cell Therapy for Neuroblastoma.” *Frontiers in Immunology*. 2018 Oct 16. doi: [10.3389/fimmu.2018.02380](https://doi.org/10.3389/fimmu.2018.02380).

## *Regulatory Incentives*

Another factor relevant to an invention's commercial value is the availability of regulatory incentives, such as orphan drug status, that provide additional market exclusivities and expedited FDA review.<sup>31</sup>

Any product embodying the invention will likely qualify for orphan drug status, expedited review, and for any indications involving rare pediatric patients, a PRV. Neuroblastoma, one of the many indications of the technology, is a rare pediatric disorder, with about 800 new cases in the United States each year.<sup>32</sup>

On March 18, 2019, GW Pharmaceuticals announced it had sold a pediatric PRV for \$105 million.<sup>33</sup>

Orphan Drug designation includes a 25% tax credit on clinical trials and seven years of market exclusivity for certain indications. As a biologic, the invention will receive 12 years of marketing exclusivity on all indications.

## *The NIH's Analysis of the License*

It is our understanding that the NIH has not undertaken a serious evaluation of the factors bearing on the invention's value, relating to practical application, in order to evaluate whether or not an exclusive license is a "reasonable and necessary incentive."

KEI asked Dr. Freel how the NIH applied the Section 209 criteria to this license to ensure that exclusivity is required and the scope of the license is not greater than necessary. She responded: "The contemplated license is for the purpose of consolidating rights of the three co-owners to allow Stanford to take the lead on behalf of all the co-owners. The intention of the prospective license is to expedite the commercial development of the invention."

Dr. Freel's response demonstrates that the NIH's analysis of the license, including the necessity of exclusivity, is inconsistent with the Bayh Dole Act. Section 209(a) does not allow federal agencies to grant fully-exclusive licenses, for life of patent, with worldwide territorial reach, whenever doing so will "expedite the commercial development of the invention."

And, while it may make sense to allow Stanford to consolidate rights in the invention for further development, that does not mean that the NIH must give Stanford the broadest possible rights without any limitations on the terms or concessions from Stanford.

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<sup>31</sup> <https://www.priorityreviewvoucher.org/>.

<sup>32</sup> <https://www.cancer.org/cancer/neuroblastoma/about/key-statistics.html>.

<sup>33</sup>

<https://www.marketwatch.com/story/gw-pharma-announces-sale-of-priority-review-voucher-for-105-million-2019-03-18-7914623>.

2. The NIH was not transparent about the government's financial contribution to the patented inventions and other matters, limiting the public's right to comment under 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely-submitted comments. 35 U.S.C. § 209(e).

For the public to meaningfully exercise its right to comment, it must have basic information about the license and the underlying invention.

KEI emailed Dr. Freel a list of questions about the license. We appreciate her response. However, without any justification for doing so, Dr. Freel refused to answer the majority of our questions. The questions that Dr. Freel refused to answer, and that are relevant to whether the license complies with federal law, pertained to the following topics:

- Stanford's role in developing the technology, as compared with NCI and CHOP;
- The proposed duration of the license;
- How much money the federal government has spent to develop the technology, including the numbers of any NIH grants associated with it; and
- How the NIH will ensure that US taxpayers receive a reasonable return on their investment in the technology.

The NIH's refusal to answer our questions about R&D expenditures continues a persistent pattern of non transparency by the NIH that is indefensible. KEI has been asking for some time about the amount of taxpayer dollars directed toward the development of publicly-funded inventions that are commercialized by the private sector. Not once has the NIH answered, nor has it provided a legitimate explanation for its failure to do so.

In this instance, Dr. Freel failed to directly explain why she could not provide an estimate of the government's contribution to the technology. Rather, she provided a blanket non-answer, stating that many of KEI's questions have already been answered, are irrelevant to the Section 209 criteria, or are business confidential.

None of these assertions passes muster. First, as KEI just noted, the NIH has never answered this question. Second, taxpayers' contribution to a patented invention bears directly on the reasonableness of the license terms, the attractiveness of investing in the technology, and the necessity of granting exclusivity.

The last assertion is the most unreasonable. There can be no valid privacy or "business confidential" reasons for refusing to disclose what the public has spent on patented inventions owned by the United States. The question KEI is asking, and which the NIH refuses to answer, does not pertain to Francis Collins' money, or Stanford's money, or private commercial partners' money. It pertains to funds that were provided by taxpayers, and taxpayers have a right to know how those funds are allocated.

There are only two possible explanations for the NIH's failure to provide this information to the public. Either the NIH is unwilling to quantify the public's investment in federally-owned or funded inventions, or it is unable to do so. Neither scenario is acceptable.

3. Under 40 U.S.C. § 559, the NIH is required to obtain the antitrust advice of the United States Attorney General before executing the license.

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license will not be anticompetitive.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property,” with certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term “property” in Section 559 includes intellectual property rights such as patents.

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

The NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

“The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.”

The NIH’s interpretation of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If the NIH has not consulted with the Attorney General regarding the license, it has not complied with 40 U.S.C. § 559.

4. In the event that the NIH decides to grant the license, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles in the PHS Technology Transfer Manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public’s interest in the technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”
3. **Global registration and affordability.** The license should require Stanford to require the sublicensee to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddi case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209,

which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

### **Concluding comments**

Any license to practice the subject invention should reflect the commercial value of the technology and U.S. taxpayers’ financial contribution toward its development. The NIH’s lack of transparency regarding the license, including the amount of federal funds that supported its basic and preclinical research, impeded KEI’s ability to precisely evaluate it, although we note that the public has spent millions of dollars on the technology. The terms of the license should reflect that investment. Before executing the license, the NIH must consult the advice of the U.S. Attorney General. If the NIH grants the license, we urge it to incorporate the provisions listed above, to safeguard the public interest in the invention and promote the policy objectives of the Bayh-Dole Act and the PHS Technology Transfer Policy Manual.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment  
Manon Ress

---

**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 11/27/2019 9:31:39 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Dutta, Mala (NIH/NEI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7548cc546a1b471b994e8095be8cd70c-ghaim]; Girards, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f43c30c4a364463bf5b2c134225b7f0-girardsrt]  
**Subject:** Fw: Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169  
**Attachments:** KEI OcQuila questions.docx

Mark, Dale, and Bruce -- KEI's questions regarding our FR notice for OcQuila are below. My responses to their questions are in the enclosed world file.

Please let me know your thoughts.

Happy Thanksgiving,

**Michael A. Shmilovich, Esq., CLP**

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Office of Technology Transfer and Development  
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**From:** Luis Gil Abinader <luis.gil.abinader@keionline.org>  
**Sent:** Wednesday, November 27, 2019 11:22 AM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Cc:** Jamie Love <james.love@keionline.org>  
**Subject:** Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

Dear Michael Shmilovich,

With regards to the prospective exclusive license to OcQuila Therapeutics, as described in the Federal Register notice located at 84 FR 65169, we would like to know the following:

- 1.
2. We appreciate the 45-days public comment period. Can you explain for us why the NIH gave an 45-days public comment period in this case, as opposed to the typical 15 days?
- 2.
3. At what stage of research and development are the inventions being licensed?

REL0000025008



- 3.
4. Are these inventions being investigated in any clinical trials? If so, can you please provide their NCT numbers?
- 4.
5. How much has the NIH spent to support the development of the inventions?
- 5.
6. Have the NIH conducted an economic analysis of what it would require to bring these inventions in to practical application?
- 6.
7. According to the licensing opportunity notices E-284-2012 and E-164-2018, a therapy based on these inventions would be eligible for Orphan Drug status. Did the NIH considered this in determining whether an exclusive license was a "reasonable and necessary" incentive?
- 7.
8. Can you provide any guidance with regards to what the NIH considers "available to the public under reasonable terms." Does this term include people around the world or just in the United States?
- 8.
9. Is the period of exclusivity to be life of patent or less than life of patent?
- 9.
10. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?
- 10.
11. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?
- 11.
12. How has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary?
- 13.
- 14.
15. What criteria was used to select OcQuila Therapeutics selected as licensee?

1. We appreciate the 45-days public comment period. Can you explain for us why the NIH gave an 45-days public comment period in this case, as opposed to the typical 15 days?

**b5**

2. At what stage of research and development are the inventions being licensed?

**b5**

3. Are these inventions being investigated in any clinical trials? If so, can you please provide their NCT numbers?

**b5**

4. How much has the NIH spent to support the development of the inventions?

**b5**

5. Have the NIH conducted an economic analysis of what it would require to bring these inventions in to practical application?

**b5**

6. According to the licensing opportunity notices E-284-2012 and E-164-2018, a therapy based on these inventions would be eligible for Orphan Drug status. Did the NIH considered this in determining whether an exclusive license was a "reasonable and necessary" incentive?

**b5**

7. Can you provide any guidance with regards to what the NIH considers "available to the public under reasonable terms." Does this term include people around the world or just in the United States?

**b5**

8. Is the period of exclusivity to be life of patent or less than life of patent?

**b5**

9. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

**b5**

10. Has the NIH sought advice from the Attorney General (as is required under 40 USC –§ 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

**b5**

11. How has/will NIH ensured that the licensing terms satisfy 35 U.S.C –§ 209(a)(2); namely, that the scope of the license is no broader than necessary?

**b5**

12. What criteria was used to select OcQuila Therapeutics selected as licensee?

**b5**

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 7/6/2020 3:19:31 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Quick Question

Hi Mark,

b5

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, July 6, 2020 10:32 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** Quick Question

Hi Dr. Burke:

Can you please confirm whether NIH completed the proposed October 2019 license to Ziopharm (84 FR 52890)?

Thank you,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

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**From:** Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]  
**Sent:** 2/24/2020 2:19:24 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: JOINT BIOETHICS COLLOQUIUM - Spring 2020 Drug Pricing February 25  
**Attachments:** Spring 2020 JBC Schedule .pdf

fyi

**From:** Goodman, Renee (NIH/CC/BEP) [E] <renee.goodman@nih.gov>  
**Sent:** Monday, February 24, 2020 9:02 AM  
**Subject:** JOINT BIOETHICS COLLOQUIUM - Spring 2020 Drug Pricing February 25  
**Importance:** High

Joint Bioethics Colloquium Tuesday, February 25<sup>th</sup> 3:30 – 5pm in the NIH Department of Bioethics Conference room (1C118), informal dinner immediately following.

**Speaker:** Jamie Love  
Knowledge Ecology International

#### Readings

A good one to actually read:

- 2009. James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer

[https://www.keionline.org/wp-content/uploads/prizes\\_new\\_medicines\\_annals\\_healthlaw.pdf](https://www.keionline.org/wp-content/uploads/prizes_new_medicines_annals_healthlaw.pdf)

Plus, time permitting, and as supplemental:

<https://delinkage.org>

<https://www.ipwatchdog.com/2019/05/15/jamie-love-responds-criticism-knowledge-ecology-international-letter/id=109239/>

<https://www.ft.com/content/06a76e44-a965-11e9-90e9-fc4b9d9528b4>Opinion Drug prices

Time to make essential cancer drugs more affordable, Governments can do more to pressure makers to bring down prices, in the FT

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<https://www.ft.com/content/06a76e44-a965-11e9-90e9-fc4b9d9528b4>, or without a password:  
[http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2019-July/023066.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2019-July/023066.html)

2014. Narmeen Haider, Aidan Hollis, James Love. "Delinkage Proposals and the Measurement of Health Benefits." Whittier Law Review, Volume 25, Number 3, Spring 2014.

2016. James Love, Delinkage Of R&D Costs From Product Prices, IP-Watch. September 15.



JOINT BIOETHICS COLLOQUIUM  
 SPRING 2019  
 DRUG PRICING

Date	Speaker	Location
January 14, 2020 Tuesday	Steven Pearson ICER	NIH
February 25, 2020 Tuesday	Jamie Love Knowledge Ecology International	NIH
March 24, 2020 Tuesday	Priti Krishtel I-MAK	NIH
April 14, 2020 Tuesday	Ezckiel Emmanuel University of Pennsylvania	NIH
April 28, 2020 Tuesday	Walter Straus Merck	NIH

All sessions meet at the NIH Clinical Center Department of Bioethics from 3:30-5:30 p.m. unless otherwise noted and are followed by an informal dinner in the Department.

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**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 11/27/2019 2:26:43 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: NIH Response to KEI

Thanks Mark – Has it been shared with NCI? Karen

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, November 27, 2019 9:15 AM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Subject:** Fwd: NIH Response to KEI

FYI: b5  
Sent from my iPhone



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**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 9/11/2019 11:35:54 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Old requests from KEI

Truvada and Pharmasset is with the agency. All others are with NIH. A few are ready to close but 1 is connected to Pharmasset. All others are dependent on compliance by institution. 1 or 2 required corrections in the patents to acknowledge NIH support.

-----Original Message-----

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 10, 2019 4:55 PM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** Old requests from KEI

Ann:

Where do the old requests sit? in the agency or department?

Thanks  
Mark

Sent from my iPhone

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**From:** Garcia-Malene, Gorka (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C4DA0F5E0A0480AAD2A86924CABA7B7-GARCIAMALEN]  
**Sent:** 7/1/2020 6:53:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Bordine, Roger (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a44282b444584690bbbe471966f54f1f-bordinerw]  
**Subject:** RE: New FOIA Request

Thanks, Mark. We will steer clear of those in our search.

Gorka

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, July 1, 2020 2:51 PM  
**To:** Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>  
**Cc:** Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>  
**Subject:** Re: New FOIA Request

Let's start with the IT search. Be careful to avoid emails that mention "love" that have nothing to do with them , eg I would love to see that document

Sent from my iPhone

On Jul 1, 2020, at 2:48 PM, Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov> wrote:

Hi Mark,

All of these are good questions. Let me address these in turn below.

**b5**

If you agree, we could ask IT to run a search on your mailbox for a sense of the volume involved. Would that help?

**b5**

**b5**

I hope this helps.

Gorka

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, July 1, 2020 2:31 PM  
**To:** Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>  
**Cc:** Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>  
**Subject:** RE: New FOIA Request

There has been a lot of email correspondence about them, hundreds of emails involving me.

b5

b5

**From:** Garcia-Malene, Gorka (NIH/OD) [E] <[gorka.garcia-malene@nih.gov](mailto:gorka.garcia-malene@nih.gov)>

**Sent:** Wednesday, July 1, 2020 2:07 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Cc:** Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>

**Subject:** New FOIA Request

Good afternoon, Mark –

Below is a FOIA request from KEI for your records. How they landed on your name, I do not know.

Under the Freedom of Information Act (5 U.S.C. § 552), Knowledge Ecology International (KEI) requests electronic copies of all correspondence to and from Dr. Mark L. Rohrbaugh, Special Advisor for Technology Transfer, that mention and/or concern the following: - “Knowledge Ecology International”, or “KEI”; -James Love; -Andrew Goldman; or -Kathryn Ardizzone. The period of this request is from January 1, 2015 to the present. (Date Range for Record Search: From 01/01/2015 To 06/18/2020)

I’m happy to chat regarding scope or any other questions you might have.

Gorka

(202) 758-9881



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

October 11, 2019

Uri Reichman, Ph.D., MBA  
Senior Licensing and Patenting Manager  
31 Center Drive, Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
Via email: [uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)

**Re: "Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," 84 FR 51171**

Dear Dr. Reichman:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) are writing to object to the prospective licenses described in the Federal Register Notice, "Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," located at 84 FR 51171<sup>1</sup> (the "Notice").

The Notice concerns two prospective licenses in a new gene therapy platform discovered by National Institute of Health (NIH) and French scientists. The first is a fully exclusive license to Generation Bio, Inc., a company that was founded by Robert Kotin, one of the NIH inventors of the technology. The second is a co-exclusive license to Generation Bio and Spark Therapeutics.

Gene therapies have attracted public attention, due to their innovative nature and high cost. Spark Therapeutics's Luxturna costs \$850,000. Zolgensma, a gene therapy to treat a rare pediatric disorder known as spinal muscular atrophy, costs \$2.1 million. Generation Bio's website and Twitter handle discuss the company's plans to develop gene therapies to treat rare pediatric disorders. The prospective licenses will likely present similar price and access issues. We also note the potential stifling effect of granting exclusive licenses in a gene therapy platform, and question whether the NIH has properly analyzed whether exclusive licensing was necessary.

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<sup>1</sup> 84 Federal Register 51171 (Sept. 27, 2019), available at <https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>.

We support the development of new biomedical inventions to cure genetic disorders. When, however, the NIH expends \$40 billion dollars of taxpayer money each year to support such research and development, it must act as a responsible steward of the public's investment.

The NIH views its mission as promoting the commercialization of taxpayer-sponsored research - without regard for other concerns. Yet Congress limited the NIH's authority to transfer the fruits of public research to the private sector, per the criteria outlined in Section 209 of the Bayh-Dole Act. The NIH may not ignore those limits, rewrite them to serve its interests, or selectively apply them.

We object to the proposed licenses on the following grounds:

1. We have concerns about the timing of the license and selection of Generation Bio as licensee;
2. Our correspondence with the NIH concerning the prospective licenses indicates that the NIH has not faithfully applied the criteria in 35 U.S.C. § 209 and 37 C.F.R. § 404, and, in particular, that it has not properly considered the reasonableness and necessity of granting an exclusive license in a platform technology for expansive fields of use;
3. The NIH has withheld information about the license on the basis of inapplicable confidentiality provisions; and
4. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

In the event that the NIH grants the license over our objections, we request that the license agreement incorporates provisions designed to safeguard the public interest and effectuate the policy objectives of the Bayh-Dole Act and the governing principles of the Public Health Service (PHS) Technology Transfer Policy Manual.

## **Background**

The Federal Register Notice "Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery" concerns two prospective licenses in one federally-owned invention - a non-viral, eukaryotic, vector-based gene therapy.

The invention is claimed in U.S. Patent No. 9,598,703, "Capsid-free AAV vectors, compositions, and methods for vector production and gene delivery" (the "703 patent"), which lists as inventors, Luis Garcia and Cyriaque Beley of France, Thomas Voit of Great Britain, and Robert Kotin and Lina Li of Maryland (NIH).

The NIH Office of Technology Transfer (OTT) assigned the invention NIH Reference No. E-241-2010, "Capsid-Free AAV Vectors for Gene Delivery and Their Use for Gene Therapy."

The invention consists of a “linear nucleic acid molecule comprising in this order: a first adeno-associated virus (AAV) terminal repeat (ITR), a nucleotide sequence of interest, and a second AAV ITR, wherein said nucleic acid molecule is devoid of AAV capsid protein coding sequences.”<sup>2</sup> It is referred to, in a PubMed article written by its inventors, as close-ended DNA.<sup>3</sup>

The OTT webpage for E-241-2010 lists the following competitive advantages of the invention:

### Competitive Advantages

- The AAV vectors described in the invention devoid the AAV capsid proteins and thus are not exposed to the adverse effects caused by immunogenicity.
- In contrast to the use of plasmid DNA for gene delivery, the AAV DNA of the invention seems to confer greater stability in cell nuclei, allowing prolonged expression compared to plasmid DNA.
- The vector DNA of the invention is not limited in size to the packageable size genome.
- The production of the AAV DNA vector is economical, simple and provides high yields.

Source: <https://www.ott.nih.gov/technology/e-241-2010>.

Similarly, the Notice describes the invention’s advantages over existing AAV gene therapies as follows:

They are advantageous over conventionally used AAV vectors, as they are non-immunogenic. They are also advantageous over plasmid-based expression constructs since they are of eukaryotic origin and thus devoid of the bacterial-type DNA methylation as typically present in plasmids.

The non-immunogenic nature of the invention could, indeed, offer a significant advantage over existing AAV gene therapies, whose potential to prompt adverse immune system reactions have been a major concern, especially after the controversial death of a pediatric clinical trial participant, Jesse Gelsinger, due to an adverse immune system response to an AAV therapy.

### Argument

1. We have concerns about the selection of Generation Bio as exclusive licensee, and the NIH’s response to our question about potential conflicts of interest have not allayed those concerns.

We noticed some peculiarities when researching the proposed licenses as they relate to Generation Bio, a biotech platform company that was founded in 2016 by Robert Kotin and Mark Angelino. Kotin was a Senior Investigator within the NIH Intramural Research Program

<sup>2</sup> <https://www.ott.nih.gov/technology/e-241-2010>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23936358>

when he helped discover the subject invention. In addition to founding Generation Bio, Kotin has been described as the company's "Head of Discovery" and "Advisor."

While we understand that NIH scientists may go on to pursue careers in the private sector, we are concerned that the NIH may have ignored the requirement in the Bayh-Dole Act to explore non-exclusive licensing of the invention, in a case where an NIH employee seeks not only to profit from invention he made while drawing a salary from the NIH, but to gain exclusive rights over an invention, blocking the ability of others to use the invention and driving up the costs of using these tools in the development of new medicines, a perverse outcome for the NIH.

Generation Bio's business platform is centered around a gene therapy that appears to be identical to the subject invention, and the company has publicized its relationship with Kotin and Kotin's role in developing its technology. In a January 4, 2018 press release, Generation Bio writes:

Our unique **capsid-free technology** enables the development of genetic medicines that can be titrated and maintained to optimally impact each patient's disease over a lifetime. In addition, it **avoids the immunogenicity associated with viral vector-based gene therapies** that limits the number of patients who can be treated and prevents re-dosing.

The company's core technology was discovered by **Generation Bio scientific founder and Head of Discovery, Robert Kotin, Ph.D.**

As a **senior investigator at the National Institutes of Health**, Dr. Kotin discovered a novel modality for non-viral gene transfer, known as **closed-ended DNA, or ceDNA**. This eukaryotic DNA has a unique ability to translocate from the cytoplasm of the cell to the nucleus **without the use of a viral capsid**. Once in the nucleus, **ceDNA** forms stable, non-integrating episomes that result in high levels of long-term gene expression.<sup>4</sup>

We have observed many other similarities between the description of Generation Bio's ceDNA in the January 2018 press release and the "capsid-free AAV vectors" claimed in the '703 patent and described on the NIH OTT webpage and Federal Register Notice. The titles of the Licensing Opportunity webpage for the invention and the Federal Register Notice both contain the phrase "Capsid-Free AAV Vectors", while the press release describes a "capsid-free technology." The press release, OTT webpage, Notice, and the '703 patent all describe an invention that avoids the immunogenicity associated with viral vector-based gene therapies. The OTT webpage links to a PubMed Article titled "Production and Characterization of Novel Recombinant Adeno-Associated Virus Replicative-Form Genomes: A Eukaryotic Source of DNA for Gene Transfer" (PMID: 23936358), which describes "closed-ended, linear duplex, or 'CELiD', DNA."

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<sup>4</sup> <https://generationbio.com/atlas-venture-launches-generation-bio/> (emphasis added).

KEI considered and investigated the possibility that Generation Bio could have been referring to some other invention developed by Kotin as an NIH scientist, but that does not seem to be the case. A search for all inventions associated with Kotin on the NIH Office of Technology Transfer website returned the following results:

Production of Adeno-Associated Viruses in Insect Cells  
Ref: E-325-2001-1 | Updated: May 9, 2018 | NHLBI  
AAV4 Vector and Uses Thereof  
Ref: E-071-2000-0 | Updated: May 9, 2018 | NHLBI  
AAV5 Vector for Transducing Brain Cells and Lung Cells  
Ref: E-072-2000-0 | Updated: May 9, 2018 | NHLBI  
AAV5 Vector and Uses Thereof  
Ref: E-127-1998-0 | Updated: May 9, 2018 | NHLBI  
AAV4 Vector And Uses Thereof  
Ref: E-066-1996-0 | Updated: May 9, 2018 | NHLBI  
Capsid-Free AAV Vectors for Gene Delivery and Their Use for Gene Therapy  
Ref: E-241-2010/0 | Updated: Oct 12, 2016 | NHLBI

Only the last invention listed, “Capsid-Free AAV Vectors for Gene Delivery and Their Use for Gene Therapy,” relates to the technology described in the Generation Bio press release. It is the same invention that is listed in the Federal Register license notice. Also, KEI searched the USPTO database for a patent that was assigned to the United States, lists Kotin as an inventor, and describes a “capsid-free AAV vector.” The ‘703 patent was the only one. Finally, the instant Notice is the only Federal Register notice in which the NIH discloses a prospective exclusive patent license to Generation Bio.

How is it that Generation Bio apparently is already discussing its proprietary rights in the technology that the NIH is here proposing to license and opening to public comment?

Generation Bio was founded on October 21, 2016. The NIH listed the E-241-2010 technology as available for licensing on October 12, 2016. Kotin clearly founded a company to profit from an invention he helped discover as an NIH employee. It appears Generation Bio received preference over other companies that applied for the license.

The NIH’s answers to our questions regarding these concerns were not helpful.

KEI asked Dr. Uri Reichman (the NIH contact listed on the Notice) for a list of the companies that applied for the licenses. He declined to provide one.

KEI asked Dr. Reichman whether the NIH “see[s] any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not?” Dr. Reichman simply responded: “No!”, ignoring the second part of KEI’s question.



We think the relationship between Kotin and Generation Bio as concerns the subject license warrants further scrutiny and explanation. Given the NIH's history with Kotin and the public's role in financing this technology, the public has a right to know how the NIH has ensured that no conflicts inhere in the proposed licenses. At minimum, we hope that, in responding to our comments, the NIH will provide a more circumspect answer to KEI's questions about the Kotin/Generation Bio relationship than "No!".

2. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license or that it has ensured that the scope of rights will not be broader than reasonably necessary to induce the investment needed to commercialize the subject technology.

Before granting an exclusive license in federally-owned technology, the agency proposing the license must find both that granting an exclusive license is a reasonable and necessary incentive and "that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" 35 U.S.C. § 209(a)(1)-(2).

We are concerned, based on Dr. Reichman's answers to our questions, that the NIH has not properly applied the limitations set forth at 35 U.S.C. § 209(a)(1)-(2).

#### *Necessity of Exclusivity*

"A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention . . . only if-- [among other things] (1) granting the license is a reasonable and necessary incentive to-- (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public[.]" 35 U.S.C. § 209(a)(1).

Consistent with Section 209(a)(1), PHS's " Best Practices for the Licensing of Genomic Inventions" announces a preference for non-exclusive licenses in genomics. It states:

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community.

When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.<sup>5</sup>

KEI asked Dr. Reichman “on what basis did the NIH conclude that an exclusive (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?”. He responded: “The license application is legally protected as confidential to the company.”

His argument about the confidentiality of license applications precluding him from addressing our question was misplaced. KEI was simply asking Dr. Reichman to articulate how the NIH determined that exclusivity was a reasonable and necessary incentive. KEI did not ask NIH to disclose any confidential elements of a license application.

Before concluding that an exclusive license is warranted, some analysis should be undertaken, such as consideration of the incentives provided by law, such as test data protection, Orphan Drug exclusivity, priority review vouchers, and the likely case that the developer can bring other patented inventions into the project, for which exclusivity exists.

Generation Bio and Spark Therapeutics appear likely to receive incentives such as the priority review voucher, orphan drug exclusivity, and test data protection for the invention, if the invention is used in connection with a drug, vaccine or cell or gene therapy.

Generation Bio seems intent on pursuing such indications as would grant them those incentives. An article on its website discusses how “the greatest therapeutic opportunity and unmet need” for gene therapies resides in pediatric patients and how “drug development programs in other pediatric orphan disorders” can track the success of Spinraza in treating SMA.<sup>6</sup> Likewise, in an article titled, “Genetic Diseases Steal Too Many Kids’ Futures. It Doesn’t Have To Be This Way[.]” Generation Bio argues that Orphan Drug Act incentives should be used to spur investment in rare pediatric diseases.<sup>7</sup>

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<sup>5</sup> *Best Practices for the Licensing of Genomic Inventions: Final Notice*, 70 Fed. Reg. 18,413 (Apr. 11, 2005), available at <https://www.govinfo.gov/content/pkg/FR-2005-04-11/pdf/05-7247.pdf>.

<sup>6</sup>

<https://generationbio.com/re-generation/right-from-the-beginning-returning-to-the-origins-of-the-orphan-drug-movement/>

<sup>7</sup> <https://www.wbur.org/cognoscenti/2018/06/08/pediatric-genetic-therapies-geoff-mcdonough>

Spark Therapeutics received Priority Review, Breakthrough Therapy, an dOrphan Drug designations and a Rare Pediatric Disease priority review voucher for Luxturna, an AAV gene therapy to treat a form of blindness caused by a mutation in the RPE65 gene.<sup>8</sup>

We also note that Roche is seeking to acquire Spark for \$4.8 billion, largely on the basis of the company's rights in NIH-funded patents and the Luxturna gene therapy.

The co-exclusive license to Spark and Generation Bio appears to be directed toward the development of a gene therapy to treat Stargardt Disease, a disease affecting 8,000 to 10,000 people worldwide. Both Spark and Generation Bio list a gene therapy to treat Stargardt as part of their product pipelines.<sup>9</sup> Generation Bio also lists, as a product in development, a gene delivery system to treat LCA10, a genetic disorder that causes childhood blindness in two to three per 100,000 people worldwide.<sup>10</sup>

Rare Pediatric Disease Priority Review Vouchers are a valuable incentive for biotech companies: Spark sold the voucher it was granted for Luxturna for \$110 million.<sup>11</sup> So, too, are Orphan drug status and FDA market exclusivity valuable to biotech companies. Orphan Drug status provides seven years of market exclusivity, commencing the day the FDA issues marketing approval on the drug. FDA-approved biologics receive 12 years test data exclusivity.

In the NIH's response to our comments, please explain if and how the NIH weighed these incentives when determining that an exclusive and co-exclusive license were necessary.

PHS has recognized that exclusive licenses are not always necessary to achieve commercial application, because companies "frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the final product."<sup>12</sup>

Generation Bio's business model appears to be centered around its "proprietary GeneWave technology, which delivers high levels of durable gene expression and can be re-dosed to titrate and sustain effect."<sup>13</sup> Please explain if NIH considered the

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<https://www.fda.gov/news-events/press-announcements/fda-approves-novel-gene-therapy-treat-patients-rare-form-inherited-vision-loss>

<sup>9</sup> <https://generationbio.com/programs/>; <https://sparktx.com/scientific-platform-programs/>

<sup>10</sup> <https://generationbio.com/programs/>

<sup>11</sup>

<http://ir.sparktx.com/news-releases/news-release-details/spark-therapeutics-sells-priority-review-voucher-110-million>

<sup>12</sup> PHS Technology Transfer Policy Board, PHS Licensing Policy (October 25, 1995) at p. 3.

<sup>13</sup> <https://generationbio.com/atlas-venture-launches-generation-bio/>

possibility that the proprietary rights in GeneWave could have provided sufficient market exclusivity.

### *Scope of the License*

Nor does it appear, from Dr. Reichman's comments in response to our questions, that the NIH has properly considered the appropriate scope of the licenses.

Before granting an exclusive license in federally-owned technology, the agency proposing the license must find "that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" 35 U.S.C. § 209(a)(2).

The scope of a license in federally-sponsored technology may vary along the following (non-exhaustive) parameters:

- The period of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (i.e., five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (i.e., targeted diseases).

The scope of a license must be not greater than necessary to incentivize a licensee to commercialize a government-owned invention. There are at least seven factors that should be considered when evaluating the necessary incentive:

1. The costs of financing research and development and bringing the invention to market, including obtaining FDA approval;
2. The government's investment in R&D and the development stage of the technology;
3. Any expected additional subsidies from governments or charities, including, for example, the Orphan Drug Tax Credit or additional grants or continued or new collaborations with the NIH or other government agencies;
4. The existence of other incentives, including, for example, test data protection, Orphan Drug exclusivity and awards of priority review vouchers;
5. The anticipated cost to manufacture the resultant invention; and
6. The expected post-market entry profitability of the invention, by year.

To apply 35 U.S.C. § 209(a)(2) with respect to a proposed exclusive license, the NIH must weigh the costs and risks associated with commercializing the government-owned technology against the probable benefits of doing so, and adjust the terms of the license accordingly.

When, for example, developing a publicly-owned invention would be a relatively less attractive prospect for investors, it may be more appropriate for the NIH to create additional incentives

through granting broad exclusive rights. On the other hand, when the risks and costs associated with developing the technology are relatively low compared to incentives that are relatively high, the NIH should negotiate a narrower license and more favorable terms for the American public.

In any event, the analysis regarding the scope of the license should be a fact-specific, case-by-case determination. If, in every instance, the NIH gives away a “sweetheart deal” in licenses in publicly-owned inventions to private companies, it is not complying with Section 209.

From what we can tell, the NIH is, once again, planning to grant the broadest possible rights in the patented invention.

#### Attractiveness of the Investment

Commercial development of the subject technology appears to be a highly attractive prospect to investors. Generation Bio has already raised upwards of \$125 million in investment capital based on the promises of its ceDNA.<sup>14</sup> Moreover, the potential patient population for the invention is large. Generation Bio is pursuing “a diverse portfolio of programs for diseases of the liver,” and “delivery systems for additional tissues, including the eye, muscle and brain.”<sup>15</sup> On its website, Generation describes how its technology “can extend the benefits of gene therapy to large diseases and global populations.”<sup>16</sup> In addition to broad disease indications, Generation envisions a large manufacturing scale: in a June 2019 presentation, CEO Geoffrey McDonough described how the company’s “[u]pstream scale unlocks production for millions of patients[.]”<sup>17</sup>

Given the lucrative potential of this technology, the breadth of its possible applications, and its potential importance to patients, the NIH should negotiate a narrower scope of rights - if it grants exclusivity in the first place. That does not appear to be the case, however, as explained below.

#### Duration of exclusivity

Perhaps the most important licensing provision, in terms of impact on price and access, is the duration of exclusivity, because it determines the length of time that the licensee can claim a monopoly on the patented invention and set whatever price the market can bear. This is a particularly sensitive concern in the area of life-threatening diseases, such as cancer, where the demand for a life-extending drug or biologic is especially inelastic, and rare diseases, where competition is limited.

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<sup>14</sup>

<https://www.biospace.com/article/generation-bio-raises-100-million-series-b-to-finance-non-viral-gene-therapy-program/>

<sup>15</sup> <https://generationbio.com/programs/>

<sup>16</sup> <https://generationbio.com/approach/>

<sup>17</sup> <https://www.jefferies.com/CMSFiles/Jefferies.com/files/Generation%20Bio.pdf>

KEI asked whether, for the proposed licenses, “[t]he period of exclusivity [or co-exclusivity] is to be life of patent or less than life of patent?” Dr. Reichman answered: “It will be negotiated. Typically exclusive licenses are for the term of the patent.”

Dr. Reichman’s statement that “[t]ypically exclusive licenses are for the term of the patent[]” is consistent with KEI’s experience with the NIH (but not with other federal agencies), and life of patent is the default period of exclusivity in NIH’s Model Exclusive Patent License Agreement.<sup>18</sup>

The NIH may not, as a routine practice, grant exclusivity for life-of-patent, without regard to whether a shorter period of time would suffice. Such a practice would violate the requirement that the scope of the license is not greater than reasonably necessary. Each invention to be licensed presents unique circumstances. If the NIH always negotiates licenses with a term of life of patent, that would strongly indicate that NIH is not accounting for those individualized circumstances.

#### Field of Use

We have significant concerns about the proposed fields of use for the licenses.

The Federal Register Notice for the prospective licenses lists the following fields of use:

*Exclusive field:* Electroporation-mediated delivery of DNA-based vectors to express therapeutic molecules for the treatment or prevention of human diseases.

*Co-exclusive field:* The treatment or prevention of cancer by administration of DNA-based vectors (with the exception of electroporation mediation) to express therapeutic molecules.

Because the phrases “treatment or prevention of human diseases” and “treatment or prevention of cancer” can be fairly characterized as vague, KEI asked: “What diseases fall within the field of use for the exclusive license to Generation Bio?” Dr. Reichman answered: “This is the broadest possible scope.”

We are concerned that the broadness of these fields of use will inhibit competition and innovation in a type of technology that has so far commanded extraordinarily high prices, limiting public access. This is inconsistent with Section 209(a)(2) and PHS’s own technology transfer policies.

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<sup>18</sup>

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Patent-License-Exclusive-model-102015.pdf>

The PHS Technology Transfer Policy Manual, Ch. 300, stipulates that PHS:

seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the invention. This enables as many companies as possible to obtain commercial development rights, resulting in the concurrent development of many potential applications and the further promotion of the invention's utilization by the public.

Similarly, PHS's Best Practices for Licensing of Genomic Inventions states that "[i]n those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible."<sup>19</sup>

We question how granting the "broadest possible field of use" in a platform gene therapy complies with Section 209(a)(2), facilitates that PHS's Technology Transfer Policy for ensuring "the appropriate scope of rights," and is consistent with Best Practices for Licensing Genomic Inventions. How do the fields of use proposed allow "concurrent development of many potential applications"?

There is widespread consensus that granting exclusive rights for the broadest possible field of use in a platform technology is bad for innovation and is certainly a bad policy for the NIH.

#### Territorial Reach

The Federal Register notice states that "the prospective exclusive license territory may be worldwide" -- the broadest possible territorial reach.

The PHS Technology Transfer Policy Manual states that "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

We question how worldwide rights in the subject technology facilitates that policy and call on the NIH to articulate its rationale for concluding that worldwide rights satisfy Section 209 and the Technology Transfer Policy quoted above.

3. The NIH has not been fully transparent about the license, impeding the public's right to comment under 35 U.S.C. 209(e).

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<sup>19</sup> *Best Practices for the Licensing of Genomic Inventions: Final Notice*, 70 Fed. Reg. 18,413 (Apr. 11, 2005), available at <https://www.govinfo.gov/content/pkg/FR-2005-04-11/pdf/05-7247.pdf>.

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely submitted comments. 35 U.S.C. § 209(e).

In order for the public to meaningfully participate in the notice-and-comment process, it must have basic information about the licenses.

The NIH has, without any legal justification, erected several barriers that prevent the public from obtaining information necessary to comment effectively on proposed exclusive licenses.

In response to many of our questions, the NIH has stated that the requested information is confidential or that the terms of a license are yet to be determined. Neither assertion is a valid basis for denying the public basic information about the licenses.

The NIH's reference to the confidentiality of license applications is not sound. Federal law and regulations make only part - not all - of a license application confidential.

The federal regulation governing confidentiality of license applications states:

**37 C.F.R. § 404.14 Confidentiality of information.**

Title 35, United States Code, section 209, requires that any plan submitted pursuant to § 404.8(h) and any report required by § 404.5(b)(6) shall be treated as commercial or financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of Title 5 of the United States Code.

37 C.F.R. § 404.14 refers to “any plan submitted pursuant to § 404.8(h)[.]” 37 C.F.R. § 404.14 (emphasis added). 37 C.F.R. § 404.8 lists 11 different components of a license application, of which only one, 37 C.F.R. § 404.8(a)(8), refers to a plan - “A detailed description of applicant's plan for development or marketing of the invention, or both[.]” The other components, listed at 37 C.F.R. § 404.8(a)(1)-(7) and (9)-(11), are not “plans” and thus are nonconfidential under § 404.14.

Section 209 of the Bayh-Dole Act refers to the confidentiality of a licensee’s “plan for development or marketing of the invention” (35 U.S.C. § 209(f)) and “periodic reporting on utilization of the invention, and utilization efforts, by the licensee” (35 U.S.C. § 209(d)(2)).

The plain language of the federal law and regulations governing exclusive licenses are clear: only the license application’s development plan and the licensees’ periodic utilization reports are confidential.



KEI emailed its interpretation of 37 C.F.R. § 404.14 as it pertains to Section 209 license applications to Dr. Reichman and to Mark Rohrbaugh, Special Advisor for Technology Transfer, NIH, and asked the NIH to explain if and why our interpretation was wrong. Neither Dr. Reichman nor Mr. Rohrbaugh responded, even after KEI submitted a follow-up request for a response.

We thus object to the licenses on the grounds that the NIH has withheld relevant information without a valid basis for doing so, impeding the public's right of comment under Section 209(e).

*4. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the licenses, as required by 40 U.S.C. 559.*

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license would not be anticompetitive.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property,” with certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term “property” in Section 559 includes intellectual property rights such as patents.

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked Dr. Reichman whether the NIH requested the advice of the U.S. Attorney General concerning the licenses. He did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

"The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations."

The NIH's interpretation of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license "will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws." 35 U.S.C. § 211 provides that "[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]" The Bayh-Dole Act sets out the areas in which the statute "shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]" 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term "disposal" is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to "assignment" or "sale." In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants a fully-exclusive license to a federally-owned invention for life of patent, and allows termination of the license only in narrow, vaguely-defined circumstances, then it is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

This is a particularly important issue in these licenses, where non-exclusive licenses to the patented inventions can and should be available to any firm developing gene therapies. The NIH is creating a monopoly where a monopoly should not exist.

5. In the event that the NIH decides to grant the licenses over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the licenses implement the governing principles in the PHS Technology Transfer Manual.

In the event that the NIH proceeds with the licenses, KEI requests that it includes the following provisions to protect the public's interest in NIH-funded technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Low and middle income countries.** The exclusive licenses should not extend to countries with a per capita income less than 30 percent of the United States, in order to

ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

3. **Global registration and affordability.** The licenses should require Generation Bio and Spark Therapeutics to disclose the steps they will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the dDI case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."
6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the

proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

## **Conclusion**

We object to the licenses for the reasons stated herein. If the NIH proceeds with the licenses over our objections, we urge that it incorporate the provisions listed herein that are designed to protect the public’s investment in this gene therapy platform.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment

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**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 2/24/2020 1:05:06 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** KEI FOIA Request  
**Attachments:** RE: Freedom of Information Act Request; FW: Freedom of Information Act Request; FW: Freedom of Information Act Request

Hi Mark – Just an FYI. We received two FOIA requests from KEI. Steve has instructed Gina to send them to the NIH FOIA Office to have them assigned to OFM directly. Regards, Karen

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**From:** Ferguson, Steve (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AEC79B088CE947819EADD4BF420AA54B-FERGUSOS]  
**Sent:** 2/22/2020 8:33:31 PM  
**To:** Thomas, Gina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a7d21227e5643548f0a7c256b54f83f-gthomas]  
**CC:** Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]  
**Subject:** RE: Freedom of Information Act Request

Gina –

For this request, please just forward it to the OD FOIA office so they (not OTT) can log it in, acknowledge the request, and direct it to the proper office (likely OFM) as this is a request for individual inventor pay information. OTT does not handle or make royalty distributions to inventors

Please do not log, acknowledge or respond to the request on behalf of OTT under any circumstances.

Thanks.

Steve

Steven M. Ferguson, CLP  
Special Advisor  
NIH Office of Technology Transfer  
6011 Executive Boulevard, Suite 325  
Rockville, MD 20852  
Phone: (301) 435-5561  
Fax: (301) 402-0220  
Email: [sf8h@nih.gov](mailto:sf8h@nih.gov)  
Web: [www.ott.nih.gov](http://www.ott.nih.gov)

**From:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>  
**Sent:** Saturday, February 22, 2020 1:36 PM  
**To:** Ferguson, Steve (NIH/OD) [E] <[fergusos@od6100m1.od.nih.gov](mailto:fergusos@od6100m1.od.nih.gov)>  
**Cc:** Rogers, Karen (NIH/OD) [E] <[rogersk@od.nih.gov](mailto:rogersk@od.nih.gov)>  
**Subject:** FW: Freedom of Information Act Request

This is one of 2 request I received directly in OTT for a response.

This is directed at Royalties. Please read the request. I will need to enter the request into the FOIA database and send an interim response noting that it was received.

Gina

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Friday, February 21, 2020 6:51 PM  
**To:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Manon Ress <[manon.ress@keionline.org](mailto:manon.ress@keionline.org)>; [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org)  
**Subject:** Freedom of Information Act Request

Dear Ms. Thomas:

Please process the attached FOIA request, submitted today on behalf of Knowledge Ecology International.

Thank you,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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**From:** Thomas, Gina (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A7D21227E5643548F0A7C256B54F83F-GTHOMAS]  
**Sent:** 2/22/2020 6:37:27 PM  
**To:** Ferguson, Steve (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec79b088ce947819eadd4bf420aa54b-fergusos]  
**CC:** Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]  
**Subject:** FW: Freedom of Information Act Request  
**Attachments:** Collins FOIA, Royalties, 21 Feb 2020.pdf

This is two of 2 request I received directly in OTT for a response.

This is directed at Royalties. Please read the request. I will need to enter the request into the FOIA database and send an interim response noting that it was received.

Gina

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, February 21, 2020 6:28 PM  
**To:** Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>  
**Cc:** James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; kei-workers <kei-workers@lists.keionline.org>  
**Subject:** Freedom of Information Act Request

Dear Ms. Thomas:

Please process the attached FOIA request, submitted today on behalf of Knowledge Ecology International. KEI will submit the request via the Online Portal as well.

Thank you in advance for processing this request.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
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February 21, 2020

Gina Thomas  
National Institutes of Health  
Office of Technology Transfer  
Room 325  
6011 Executive Blvd.  
Rockville, MD 20852  
Via Email: [gthomas@mail.nih.gov](mailto:gthomas@mail.nih.gov)

Dear Ms. Thomas:

Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests all records, of any kind, that mention royalty payments to Francis S. Collins, Ph.D., Director of the National Institutes of Health (NIH), from 2009 to present.

KEI is willing to consider narrowing the timeframe of this request if it would expedite a response.

### **Context for the Request**

KEI appreciates Dr. Collins' admirable accomplishments in advancing biomedical innovation and promoting access to research within the scientific community.

While Dr. Collins' performance in advancing medical science is laudable, KEI has been surprised, frustrated, and concerned about Dr. Collins' decisions regarding the licensing of NIH-owned inventions, and the lack of transparency surrounding NIH licenses. Under Dr. Collins' leadership, the NIH has concealed information about royalty payments to its employees, blocked efforts to learn about the costs of clinical trials funded and in some cases performed by the NIH, and repeatedly misrepresented the legal obligations of holders of NIH-funded patents to make the benefits of inventions available to the public on reasonable terms.

KEI has observed a culture at the NIH that protects licenses of NIH-funded inventions from transparency and obligations regarding the affordability of government funded drugs, vaccines, and cell and gene therapies.

KEI has an interest in knowing the extent to which NIH employees, past and present, including Dr. Collins, personally benefit from the high and unaffordable prices of new government-funded medical technologies. The royalty payments, if any, to Dr. Collins, are relevant to this question.

### **Inapplicability of FOIA Exemptions**

In denying a previous and related, but differently-worded request for royalties information, the NIH Office of Technology Transfer (OTT) withheld records pursuant to Exemptions 3 and 4 of the FOIA.

FOIA Exemptions 3 and 4 do not justify withholding records that are responsive to this request.

In withholding records under Exemption 3, which pertains to records that are exempt from disclosure by another federal statute, the OTT invoked 15 U.S.C. § 3710a(c)(7)(A). Section 3710a(c)(7)(A) protects from disclosure:

trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement[.]

FOIA Exemption 4, codified at 5 U.S.C. § 552(b)(4), protects “trade secrets and commercial or financial information obtained from a person and privileged or confidential[.]”

This request does not require disclosure of “trade secrets or commercial or financial information that is privileged or confidential” within the meaning of the FOIA.

This FOIA request is directed only at royalty payments received by Dr. Collins, who is a federal employee. We are not requesting the identity of the private companies that provided those payments.

KEI does not object to the redaction of any information apart from the royalty payment amount.

The disclosed records will not be traceable to a particular licensee. Dr. Collins is listed as an inventor on patents that involve several other inventors and assignees. As such, the royalty payment records will not be traceable to the firm that paid the royalty.

To be more specific, it is our understanding that Dr. Collins is listed as an inventor on at least 16 patents that are assigned to the United States. These patents were filed from 1997 to 2017.

*Most had multiple assignees.*

Three of the 16 patents were only assigned to the United States, but 13 of the patents were assigned to multiple entities. Twelve of the patents had three or more assignees.

*All had multiple inventors.*

All of the patents listed more than one inventor. Fifteen of the 16 patents had more than two inventors. Eleven of the 16 patents had more than four inventors.

This data is presented in Table 1.

For any given year that we are requesting royalty payment information, it is impossible to know how much money a specific licensee paid in royalties to the NIH, from this FOIA request.

**Table 1: Patents in Which Francis Collins is Listed as an Inventor and Which Include an Assignment to the United States of America, According to the USPTO PatFT Database.**

Patent No.	Patent Title	Filing Date	No. of Assignees	No. of Inventors	Inventors' Names
<u>6,013,449</u>	<u>Probe-based analysis of heterozygous mutations using two-color labelling</u>	Nov 26, 1997	1	3	Hacia; Joseph G. (Rockville, MD), Chee; Mark S. (Palo Alto, CA), Collins; Francis S. (Rockville, MD)
<u>6,211,336</u>	<u>Ataxia-telangiectasia gene</u>	Nov 26, 1997	1	3	Shiloh; Yosef (Tel Aviv, IL), Tagle; Danilo A. (Gaithersburg, MD), Collins; Francis (Rockville, MD)
<u>6,342,355</u>	<u>Probe-based analysis of heterozygous mutations using two-color labelling</u>	Jan 5, 2000	2	2	Hacia; Joseph G. (Rockville, MD), Chee; Mark S. (Palo Alto, CA), Collins; Francis S. (Rockville, MD)

<u>6,627,745</u>	<u>Pyrin gene and mutants thereof, which cause familial Mediterranean fever</u>	Aug 7, 2000	6	14	Kastner; Daniel L. (Bethesda, MD), Aksentijevich; Ivona (Bethesda, MD), Centola; Michael (Tacoma Park, MD), Deng; Zuoming (Gaithersburg, MD), Sood; Ramen (Rockville, MD), Collins; Francis S. (Rockville, MD), Blake; Trevor (Laytonsville, MD), Liu; P. Paul (Ellicott City, MD), Fischel-Ghodsian; Nathan (Los Angeles, CA), Gumucio; Deborah L. (Ann Arbor, MI), Richards; Robert I. (North Adelaide, AU), Ricke; Darrell O. (San Diego, CA), Doggett; Norman A. (Santa Cruz, NM), Pras; Mordechai (Tel-Hashomer, IL)
<u>7,297,492</u>	<u>LMNA gene and its involvement in Hutchinson-Gilford Progeria Syndrome (HGPS) and arteriosclerosis</u>	Sep 17, 2004	3	4	Eriksson; B. Maria H. (Solna, SE), Collins; Francis S. (Rockville, MD), Gordon; Leslie B. (Foxboro, MA), Brown; W. Ted (Staten Island, NY)
<u>7,358,347</u>	<u>MEN1, the gene associated with multiple endocrine neoplasia type 1, menin polypeptides and uses thereof</u>	Mar 4, 1998	13	13	Chandrasekharappa; Settara (Gaithersburg, MD), Guru; Siradanahalli (Bethesda, MD), Manickam; Pachiappan (Huntsville, AL), Collins; Francis S. (Rockville, MD), Emmert-Buck; Michael R. (Silver Spring, MD), Debelenko; Larisa V. (New York, NY), Lubensky; Irina A. (Silver Spring, MD), Liotta; Lance A. (Bethesda, MD), Agarwal; Sunita K. (Gaithersburg, MD), Spiegel; Allen M. (Bethesda, MD), Burns; A. Lee (Rockville, MD), Marx; Stephen J. (Chevy Chase, MD), Zhuang; Zhengping (Bethesda, MD)
<u>7,838,531</u>	<u>Farnesyltransferase inhibitors for treatment of laminopathies, cellular aging and atherosclerosis</u>	Jul 25, 2007	4	7	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Rumson, NJ), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)

<u>8,034,557</u>	<u>LMNA gene and its involvement in Hutchinson-Gilford Progeria Syndrome (HGPS) and arteriosclerosis</u>	Oct 10, 2007	3	4	Eriksson; B. Maria H. (Solna, SE), Collins; Francis S. (Rockville, MD), Gordon; Leslie B. (Foxboro, MA), Brown; W. Ted (Staten Island, NY)
<u>8,257,915</u>	<u>Farnesyltransferase inhibitors for treatment of laminopathies, cellular aging and atherosclerosis</u>	Oct 15, 2010	4	7	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Rumson, NJ), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)
<u>8,535,884</u>	<u>LMNA gene and its involvement in Hutchinson-Gilford Progeria Syndrome (HGPS) and arteriosclerosis</u>	Sep 9, 2011	3	4	Eriksson; B. Maria H. (Solna, SE), Collins; Francis S. (Rockville, MD), Gordon; Leslie B. (Foxboro, MA), Brown; W. Ted (Staten Island, NY)
<u>8,691,501</u>	<u>Farnesyltransferase inhibitors for treatment of laminopathies, cellular aging and atherosclerosis</u>	Aug 6, 2012	4	7	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Rumson, NJ), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)
<u>8,828,356</u>	<u>Farnesyltransferase inhibitors for treatment of laminopathies, cellular aging and atherosclerosis</u>	Apr 4, 2013	4	7	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Philadelphia, PA), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)
<u>9,115,400</u>	<u>LMNA gene and its involvement in Hutchinson-Gilford Progeria Syndrome (HGPS) and</u>	Sep 12, 2013	3	4	Eriksson; B. Maria H. (Stockholm, SE), Collins; Francis S. (Rockville, MD), Gordon; Leslie B. (Foxboro, MA), Brown; William Ted (Staten Island, NY)

	<u>arteriosclerosis</u>				
<u>9,326,992</u>	<u>Methods for</u> <u>treating</u> <u>progeroid</u> <u>laminopathies</u> <u>using</u> <u>oligonucleotide</u> <u>analogues</u> <u>targeting</u> <u>human LMNA</u>	<u>Decemb</u> <u>er 7,</u> <u>2012</u>	<u>3</u>	<u>4</u>	<u>Eriksson; B. Maria H. (Stockholm, SE),</u> <u>Collins; Francis S. (Rockville, MD),</u> <u>Gordon; Leslie B. (Foxboro, MA),</u> <u>Brown; William Ted (Staten Island, NY)</u>
<u>9,833,468</u>	<u>Methods for</u> <u>treating</u> <u>progeroid</u> <u>laminopathies</u> <u>using</u> <u>oligonucleotide</u> <u>analogues</u> <u>targeting</u> <u>human LMNA</u>	<u>Mar 29,</u> <u>2016</u>	<u>3</u>	<u>4</u>	<u>Kole; Ryszard (Corvallis, OR), Collins;</u> <u>Francis S. (Chevy Chase, MD), Erdos;</u> <u>Michael R. (Severna Park, MD), Cao;</u> <u>Kan (Bowie, MD)</u>
<u>10,398,721</u>	<u>Methods for</u> <u>treating</u> <u>progeroid</u> <u>laminopathies</u> <u>using</u> <u>oligonucleotide</u> <u>analogues</u> <u>targeting</u> <u>human LMNA</u>	<u>Oct 6,</u> <u>2017</u>	<u>4</u>	<u>5</u>	<u>Kole; Ryszard (Corvallis, OR), Collins;</u> <u>Francis S. (Chevy Chase, MD), Erdos;</u> <u>Michael R. (Severna Park, MD), Cao;</u> <u>Kan (Bowie, MD), Gordon; Leslie B.</u> <u>(Foxboro, MA)</u>

### Request for Full Waiver of Fees

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A) and 45 C.F.R. § 5.45, which stipulate that FOIA fees must be waived where disclosure "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government," and "is not primarily in the commercial interest of the requester."

The subject of this request concerns the operations of the federal government because it pertains to Dr. Collins' receipt of royalty payments as compensation for inventions that he developed in his capacity as a federal employee.

The disclosures will likely contribute to public understanding of the extent to which an NIH employee's interest in the prices of NIH funded inventions may have affected his official actions.

KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *the Financial Times* and in several academic and policy journals, and has been named as one of the 50 most influential persons in intellectual property, by *Managing Intellectual Property*, three times, including in 2019.<sup>1</sup>

The stories listed in Annex 1 demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. See *Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

### **Additional Comments**

Please provide the documents requested in electronic format.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org).

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<sup>1</sup> <https://www.managingip.com/Article/3907375/The-50-most-influential-people-in-IP-2019.html>.

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
[Kathryn.ardizzone@keionline.org](mailto:Kathryn.ardizzone@keionline.org)

Luis Gil Abinader  
Research Associate  
Knowledge Ecology International  
[Luis.gil.abinader@keionline.org](mailto:Luis.gil.abinader@keionline.org)

**ANNEX 1**



KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates websites including [keionline.org](http://keionline.org) and [drugdatabase.info](http://drugdatabase.info) that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as [ip-health](http://ip-health.org), which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at [keionline.org](http://keionline.org).

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests in the open source database [drugdatabase.info](http://drugdatabase.info):

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/ni-h-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. Front page.
- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," *Inside Views, IP-Watch.Org*.

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**From:** Thomas, Gina (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A7D21227E5643548F0A7C256B54F83F-GTHOMAS]  
**Sent:** 2/22/2020 6:36:21 PM  
**To:** Ferguson, Steve (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec79b088ce947819eadd4bf420aa54b-fergusos]  
**CC:** Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]  
**Subject:** FW: Freedom of Information Act Request  
**Attachments:** KEI FOIA, NIH Royalties for Six Employees, 21 Feb 2020.pdf

This is one of 2 request I received directly in OTT for a response.

This is directed at Royalties. Please read the request. I will need to enter the request into the FOIA database and send an interim response noting that it was received.

Gina

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, February 21, 2020 6:51 PM  
**To:** Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>  
**Cc:** James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Manon Ress <manon.ress@keionline.org>; kei-foia-request@keionline.org  
**Subject:** Freedom of Information Act Request

Dear Ms. Thomas:

Please process the attached FOIA request, submitted today on behalf of Knowledge Ecology International.

Thank you,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

February 21, 2020

Gina Thomas  
National Institutes of Health  
Office of Technology Transfer  
Room 325  
6011 Executive Blvd.  
Rockville, MD 20852  
Via Email: [gthomas@mail.nih.gov](mailto:gthomas@mail.nih.gov)

Dear Ms. Thomas:

Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests all records, of any kind, that mention royalty payments to any or all of the following individuals: Brian Murphy; Crystal Mackall; Dimiter Dimitrov; John Schiller; Robert Kotin; and Steven Rosenberg (collectively, "the NIH employees").

The time period of the request is 1985 to present. KEI is willing to consider narrowing this timeframe if it would expedite a response.

### **Context for the Request**

KEI has an interest in knowing the extent to which NIH employees, past and present, personally benefit from the high and unaffordable prices of new government-funded medical technologies. The royalty payments to the individuals listed above, who are all current or former NIH employees, are relevant to this question.

### **Inapplicability of FOIA Exemptions**

In denying a previous and related, but differently-worded request for royalties information, the NIH Office of Technology Transfer (OTT) withheld records pursuant to Exemptions 3 and 4 of the FOIA.

FOIA Exemptions 3 and 4 do not justify withholding records that are responsive to this request.

In withholding records under Exemption 3, which pertains to records that are exempt from disclosure by another federal statute, the OTT invoked 15 U.S.C. § 3710a(c)(7)(A). Section 3710a(c)(7)(A) protects from disclosure:

trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement[.]

FOIA Exemption 4, codified at 5 U.S.C. § 552(b)(4), protects “trade secrets and commercial or financial information obtained from a person and privileged or confidential[.]”

This request does not require disclosure of “trade secrets or commercial or financial information that is privileged or confidential” within the meaning of the FOIA.

This FOIA request is directed only at royalty payments received by the individuals listed above, for inventions they discovered or conceptualized in their capacity as a federal employee. We are not requesting the identity of the private companies that provided those payments.

KEI does not object to the redaction of any information apart from the royalty payment amount.

Annex 1 lists all patents of which KEI is aware in which one of the NIH employees is listed as an inventor, and the United States of America is listed as an assignee.

The total number of patents for each employee ranges from seven (Crystal Mackall) to as high as 85 patents (Steven Rosenberg). In most cases, the individual patents list several inventors.

For any given year that we are requesting royalty payment information, it is impossible to know how much money a specific licensee paid in royalties to the NIH, from this FOIA request.

Since each inventor has several patents, and among them are patents with several inventors and in some cases, several assignees, and payments from the federal government to an inventor combine royalties from all patents for which the inventor has an interest, it is not possible to trace the payments from the inventor to a particular license.

### **Request for Full Waiver of Fees**

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A) and 45 C.F.R. § 5.45, which stipulate that FOIA fees must be waived where disclosure “is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government,” and “is not primarily in the commercial interest of the requester.”

The subject of this request concerns the operations of the federal government because it pertains to the NIH employees' receipt of royalty payments as compensation for inventions that they developed or conceptualized in their capacity as a federal employee.

The disclosures will likely contribute to public understanding of the extent to which an NIH employee's interest in the prices of NIH funded inventions may have affected his or her official actions.

KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *the Financial Times* and in several academic and policy journals, and has been named as one of the 50 most influential persons in intellectual property, by *Managing Intellectual Property*, three times, including in 2019.<sup>1</sup>

The stories listed in Annex 2 demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. See *Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

### **Additional Comments**

Please provide the documents requested in electronic format.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

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<sup>1</sup> <https://www.managingip.com/Article/3907375/The-50-most-influential-people-in-IP-2019.html>.

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org).

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
[Kathryn.ardizzone@keionline.org](mailto:Kathryn.ardizzone@keionline.org)

Luis Gil Abinader  
Research Associate  
Knowledge Ecology International  
[Luis.gil.abinader@keionline.org](mailto:Luis.gil.abinader@keionline.org)

## ANNEX 1

Inventor	Patent	Title	Filing Date
Brian Murphy	<u>7,201,907</u>	<u>Attenuated human-bovine chimeric parainfluenza virus(PIV) vaccines</u>	June 1, 2000
Brian Murphy	<u>7,208,161</u>	<u>Production of attenuated parainfluenza virus vaccines from cloned nucleotide sequences</u>	May 22, 1998
Brian Murphy	<u>7,226,602</u>	<u>Development of mutations useful for attenuating dengue viruses and chimeric dengue viruses</u>	November 21, 2003
Brian Murphy	<u>7,314,631</u>	<u>Use of recombinant live-attenuated parainfluenza virus (PIV) as a vector to protect against disease caused by PIV and respiratory syncytial virus (RSV)</u>	December 10, 1999
Brian Murphy	<u>7,465,794</u>	<u>Polynucleotides encoding recombinant respiratory syncytial viruses expressing immune modulatory molecules</u>	January 8, 2004
Brian Murphy	<u>7,485,440</u>	<u>Production of attenuated respiratory syncytial virus vaccines involving modification of M2 ORF2</u>	December 13, 2004
Brian Murphy	<u>7,504,109</u>	<u>Influenza hemagglutinin and neuraminidase variants</u>	May 20, 2005
Brian Murphy	<u>7,517,531</u>	<u>Dengue tetravalent vaccine containing a common 30 nucleotide deletion in the 3'-UTR of dengue types 1,2,3, and 4, or antigenic chimeric dengue viruses 1,2,3, and 4</u>	October 21, 2004
Brian Murphy	<u>7,560,118</u>	<u>Attenuated dengue virus comprising mutations in the NS3 gene</u>	June 2, 2006
Brian Murphy	<u>7,622,123</u>	<u>Attenuated human-bovine chimeric parainfluenza virus (PIV) vaccines</u>	November 4, 2004
Brian Murphy	<u>7,662,397</u>	<u>Respiratory syncytial virus vaccines expressing protective antigens from promoter-proximal genes</u>	February 8, 2005
Brian Murphy	<u>7,704,491</u>	<u>Recombinant human metapneumovirus and its use</u>	February 27, 2004
Brian Murphy	<u>7,709,007</u>	<u>Production of attenuated respiratory syncytial virus vaccines from cloned nucleotide sequences</u>	September 2, 2004



Brian Murphy	<u>7,744,902</u>	<u>Respiratory syncytial virus vaccines expressing protective antigens from promotor-proximal genes</u>	January 10, 2005
Brian Murphy	<u>7,820,181</u>	<u>Recovery of recombinant human parainfluenza virus type 2 (HPIV2) from cDNA and use of recombinant HPIV2 in immunogenic compositions and as vectors to elicit immune responses against PIV and other human pathogens</u>	September 18, 2003
Brian Murphy	<u>7,820,182</u>	<u>Production of attenuated, human-bovine chimeric respiratory syncytial viruses for use in immunogenic compositions</u>	November 7, 2003
Brian Murphy	<u>7,829,102</u>	<u>Production of attenuated, human-bovine chimeric respiratory syncytial virus vaccines</u>	March 31, 2005
Brian Murphy	<u>7,842,798</u>	<u>Production of attenuated, human-bovine chimeric respiratory syncytial virus vaccines</u>	August 11, 2005
Brian Murphy	<u>7,846,455</u>	<u>Attenuated chimeric respiratory syncytial virus</u>	November 25, 2003
Brian Murphy	<u>7,919,301</u>	<u>Recovery of recombinant human parainfluenza virus type 2 (HPIV2) from CDNA and use of recombinant HPIV2 in immunogenic compositions and as vectors to elicit immune responses against PIV and other human pathogens</u>	September 28, 2007
Brian Murphy	<u>7,951,383</u>	<u>Attenuated parainfluenza virus (PIV) vaccines</u>	April 17, 2007
Brian Murphy	<u>8,039,003</u>	<u>Recombinant attenuated dengue viruses comprising a deletion in the 3' untranslated region and additional attenuating mutations induced by chemical mutagenesis</u>	March 2, 2009
Brian Murphy	<u>8,075,903</u>	<u>Denque tetravalent vaccine containing a common 30 nucleotide deletion in the 3'-UTR of dengue types 1, 2, 3, and 4 or antigenic chimeric dengue viruses 1, 2, 3, and 4</u>	March 4, 2009
Brian Murphy	<u>8,168,202</u>	<u>Hexavalent bovine rotavirus reassortant composition designed for use in developing countries</u>	July 7, 2006
Brian Murphy	<u>8,298,541</u>	<u>Live attenuated virus vaccines for La Crosse virus and other Bunyaviridae</u>	March 6, 2008

Brian Murphy	<u>8,337,860</u>	<u>Development of dengue virus vaccine components</u>	August 15, 2007
Brian Murphy	<u>8,367,074</u>	<u>Recovery of recombinant human parainfluenza virus type 2 (HYPV2) from cDNA and use of recombinant HYPV2 in immunogenic compositions and as vectors to elicit immune responses against PIV and other human pathogens</u>	September 27, 2007
Brian Murphy	<u>8,568,739</u>	<u>Antigenic chimeric tick-borne encephalitis virus/dengue virus type 4 recombinant viruses</u>	May 28, 2010
Brian Murphy	<u>8,632,782</u>	<u>Recombinant attenuated dengue viruses comprising mutations in NS5 and the 3' untranslated region</u>	September 22, 2011
Brian Murphy	<u>8,778,671</u>	<u>Construction of West Nile virus and dengue virus chimeras for use in a live virus vaccine to prevent disease caused by West Nile virus</u>	June 18, 2004
Brian Murphy	<u>9,034,343</u>	<u>Attenuated human parainfluenza virus, methods and uses thereof</u>	January 10, 2006
Brian Murphy	<u>9,090,873</u>	<u>Development of dengue virus vaccine components</u>	December 3, 2012
Brian Murphy	<u>9,238,799</u>	<u>Antigenic chimeric tick-borne encephalitis virus/dengue virus type 4 recombinant viruses</u>	August 30, 2013
Brian Murphy	<u>9,624,475</u>	<u>Genetically stable live attenuated respiratory syncytial virus vaccine and its production</u>	March 13, 2013
Brian Murphy	<u>9,707,287</u>	<u>Attenuated mutant dengue viruses comprising a mutation in the NS4B non-structural protein</u>	December 4, 2013
Brian Murphy	<u>9,783,787</u>	<u>Dengue tetravalent vaccine containing a common 30 nucleotide deletion in the 3'-UTR of dengue types 1, 2, 3, and 4, or antigenic chimeric dengue viruses 1, 2, 3, and 4</u>	November 28, 2011
Brian Murphy	<u>9,884,104</u>	<u>Live attenuated virus vaccines for la crosse virus and other bunyaviridae</u>	February 8, 2016
Brian Murphy	<u>10,058,602</u>	<u>Construction of West Nile virus and dengue virus chimeras for use in a live virus vaccine to prevent disease caused by West Nile virus</u>	June 16, 2014
Brian Murphy	<u>10,160,957</u>	<u>Development of dengue virus vaccine components</u>	June 17, 2015

Brian Murphy	<u>10,206,995</u>	<u>Live attenuated virus vaccines for la crosse virus and other bunyaviridae</u>	<u>December 21, 2017</u>
Brian Murphy	<u>10,307,476</u>	<u>Genetically stable live attenuated respiratory syncytial virus vaccine and its production</u>	<u>March 10, 2017</u>
Brian Murphy	<u>10,456,461</u>	<u>Construction of West Nile virus and dengue virus chimeras for use in a live virus vaccine to prevent disease caused by West Nile virus</u>	<u>July 2, 2018</u>
Brian Murphy	<u>10,500,264</u>	<u>Development of mutations useful for attenuating dengue viruses and chimeric dengue viruses</u>	<u>July 14, 2017</u>
Brian Murphy	<u>10,561,724</u>	<u>Live attenuated virus vaccines for La Crosse virus and other bunyaviridae</u>	<u>January 4, 2019</u>
Brian Murphy	<u>RE45,016</u>	<u>Development of mutations useful for attenuating dengue viruses and chimeric dengue viruses</u>	<u>May 17, 2013</u>
Brian Murphy	<u>RE45,053</u>	<u>Attenuated dengue virus comprising mutations in the NS3 gene</u>	<u>May 17, 2013</u>
Brian Murphy	<u>RE45,123</u>	<u>Recombinant attenuated dengue viruses comprising a deletion in the 3' untranslated region and additional attenuating mutations induced by chemical mutagenesis</u>	<u>May 17, 2013</u>
Brian Murphy	<u>RE46,042</u>	<u>Development of dengue virus vaccine components</u>	<u>May 16, 2013</u>
Brian Murphy	<u>RE46,631</u>	<u>Dengue tetravalent vaccine containing a common 30 nucleotide deletion in the 3'-UTR of dengue types 1,2,3, and 4, or antigenic chimeric dengue viruses 1,2,3, and 4</u>	<u>May 17, 2013</u>
Brian Murphy	<u>RE46,641</u>	<u>Dengue tetravalent vaccine containing a common 30 nucleotide deletion in the 3'-UTR of dengue types 1,2,3, and 4, or antigenic chimeric dengue viruses 1,2,3, and 4</u>	<u>May 17, 2013</u>
Crystal Mackall	<u>7,867,977</u>	<u>Immunogenic peptides and methods of use for treating and preventing cancer</u>	<u>October 24, 2006</u>
Crystal Mackall	<u>8,614,304</u>	<u>Immunogenic peptides and methods of use for treating and preventing cancer</u>	<u>December 13, 2010</u>
Crystal Mackall	<u>9,206,245</u>	<u>Immunogenic peptides and methods of use for treating and preventing cancer</u>	<u>December 20, 2013</u>

Crystal Mackall	<u>9,790,282</u>	<u>Anti-CD276 polypeptides, proteins, and chimeric antigen receptors</u>	March 24, 2014
Crystal Mackall	<u>9,868,774</u>	<u>Anti-CD22 chimeric antigen receptors</u>	October 19, 2012
Crystal Mackall	<u>10,072,078</u>	<u>M971 chimeric antigen receptors</u>	September 18, 2013
Crystal Mackall	<u>10,562,952</u>	<u>Anti-CD276 chimeric antigen receptors</u>	September 9, 2016
Dimiter Dimitrov	<u>7,223,844</u>	<u>Broadly cross-reactive neutralizing antibodies against human immunodeficiency virus selected by Env-CD4-co-receptor complexes</u>	October 16, 2002
Dimiter Dimitrov	<u>7,378,093</u>	<u>Broadly cross-reactive neutralizing antibodies against Human Immunodeficiency Virus selected by Env-CD4-co-receptor complexes</u>	May 15, 2007
Dimiter Dimitrov	<u>7,566,451</u>	<u>Human immunodeficiency virus-neutralizing human antibodies with improved breadth and potency</u>	May 6, 2003
Dimiter Dimitrov	<u>7,803,913</u>	<u>Identification of novel broadly cross-reactive neutralizing human monoclonal antibodies using sequential antigen panning of phage display libraries</u>	May 6, 2003
Dimiter Dimitrov	<u>7,824,681</u>	<u>Human monoclonal antibodies that specifically bind IGF-II</u>	August 15, 2006
Dimiter Dimitrov	<u>7,988,971</u>	<u>Human monoclonal antibodies against Hendra and Nipah viruses</u>	November 4, 2005
Dimiter Dimitrov	<u>8,071,323</u>	<u>Human monoclonal antibodies that bind human insulin like growth factors and their use</u>	April 6, 2007
Dimiter Dimitrov	<u>8,105,598</u>	<u>Human monoclonal antibodies that specifically bind IGF-II</u>	September 23, 2010
Dimiter Dimitrov	<u>8,110,192</u>	<u>Human immunodeficiency virus type 1 (HIV-1)-neutralizing human single-chain antibodies with improved breadth and potency</u>	July 24, 2009
Dimiter Dimitrov	<u>8,313,746</u>	<u>Human monoclonal antibodies against hendra and nipah viruses</u>	August 1, 2011
Dimiter Dimitrov	<u>8,357,783</u>	<u>Human anti-mesothelin monoclonal antibodies</u>	March 25, 2009
Dimiter Dimitrov	<u>8,580,927</u>	<u>Engineered antibody constant domain molecules</u>	January 30, 2009

Dimiter Dimitrov	<u>8,591,889</u>	<u>Human monoclonal antibodies specific for CD22</u>	April 1, 2009
Dimiter Dimitrov	<u>8,858,938</u>	<u>Human monoclonal antibodies against Hendra and Nipah viruses</u>	September 13, 2013
Dimiter Dimitrov	<u>8,871,206</u>	<u>Anti-human folate receptor beta antibodies and methods of use</u>	March 8, 2013
Dimiter Dimitrov	<u>8,911,728</u>	<u>High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins</u>	May 20, 2011
Dimiter Dimitrov	<u>9,044,457</u>	<u>Anti-DR4 agonist antibodies</u>	June 16, 2011
Dimiter Dimitrov	<u>9,056,907</u>	<u>Human domain antibodies against components of the human insulin-like growth factor (IGF) system</u>	October 7, 2010
Dimiter Dimitrov	<u>9,127,056</u>	<u>Monospecific and bispecific human monoclonal antibodies targeting insulin-like growth factor II (IGF-II)</u>	October 16, 2012
Dimiter Dimitrov	<u>9,150,644</u>	<u>Human monoclonal antibodies that bind insulin-like growth factor (IGF) I and II</u>	April 11, 2012
Dimiter Dimitrov	<u>9,181,327</u>	<u>Anti-HIV domain antibodies and method of making and using same</u>	January 7, 2009
Dimiter Dimitrov	<u>9,206,257</u>	<u>Human monoclonal antibodies specific for glypican-3 and use thereof</u>	April 19, 2012
Dimiter Dimitrov	<u>9,279,019</u>	<u>Human monoclonal antibodies specific for CD22</u>	August 5, 2013
Dimiter Dimitrov	<u>9,416,190</u>	<u>Mesothelin antibodies and methods for eliciting potent antitumor activity</u>	September 16, 2013
Dimiter Dimitrov	<u>9,527,903</u>	<u>Engineered antibody constant domain molecules</u>	October 1, 2013
Dimiter Dimitrov	<u>9,598,492</u>	<u>Human monoclonal antibodies specific for CD22</u>	February 1, 2016
Dimiter Dimitrov	<u>9,657,096</u>	<u>Human domain antibodies against components of the human insulin-like growth factor (IGF) system</u>	May 13, 2015
Dimiter Dimitrov	<u>9,676,846</u>	<u>Human monoclonal antibodies that bind insulin-like growth factor (IGF) I and II</u>	August 21, 2015
Dimiter Dimitrov	<u>9,676,857</u>	<u>Soluble engineered monomeric Fc</u>	March 14, 2013
Dimiter Dimitrov	<u>9,738,726</u>	<u>HER2-specific monoclonal antibodies and conjugates thereof</u>	June 9, 2014

Dimiter Dimitrov	<u>9,765,142</u>	<u>TEM8 antibodies and their use in treatment and detection of tumors</u>	October 13, 2014
Dimiter Dimitrov	<u>9,790,282</u>	<u>Anti-CD276 polypeptides, proteins, and chimeric antigen receptors</u>	March 24, 2014
Dimiter Dimitrov	<u>9,932,406</u>	<u>Human monoclonal antibodies specific for glypican-3 and use thereof</u>	April 5, 2016
Dimiter Dimitrov	<u>10,072,078</u>	<u>M971 chimeric antigen receptors</u>	September 18, 2013
Dimiter Dimitrov	<u>10,196,443</u>	<u>TEM8 antibodies and their use in treatment and detection of tumors</u>	August 17, 2017
Dimiter Dimitrov	<u>10,287,340</u>	<u>Anti-HIV domain antibodies and method of making and using same</u>	September 28, 2015
Dimiter Dimitrov	<u>10,323,083</u>	<u>Agents that specifically bind matrilin-3 and their use</u>	January 14, 2015
Dimiter Dimitrov	<u>10,358,481</u>	<u>Engineered antibody constant domain molecules</u>	December 2, 2016
Dimiter Dimitrov	<u>10,421,802</u>	<u>Human monoclonal antibodies against the middle east respiratory syndrome coronavirus (MERS-CoV) and engineered bispecific fusions with inhibitory peptides</u>	October 16, 2014
Dimiter Dimitrov	<u>10,428,141</u>	<u>Compositions and methods for treating cancer with anti-ROR1 immunotherapy</u>	November 2, 2018
Dimiter Dimitrov	<u>10,434,174</u>	<u>Combination therapies using platinum agents and agents that target tumor-associated stroma or tumor cells</u>	June 9, 2015
Dimiter Dimitrov	<u>10,472,412</u>	<u>Bispecific multivalent fusion proteins</u>	December 16, 2015
Dimiter Dimitrov	<u>10,494,435</u>	<u>Human monoclonal antibodies specific for CD22</u>	February 3, 2017
Dimiter Dimitrov	<u>10,501,539</u>	<u>Compositions and methods for treating cancer with anti-CD19 immunotherapy</u>	September 14, 2018
Dimiter Dimitrov	<u>10,538,588</u>	<u>Mesothelin-targeted chimeric antigen receptors and methods of making them</u>	May 16, 2018
Dimiter Dimitrov	<u>10,543,263</u>	<u>Compositions and methods for treating cancer with anti-CD22 immunotherapy</u>	October 16, 2018
Dimiter Dimitrov	<u>10,548,987</u>	<u>Antibody-drug conjugates for targeting CD56-positive tumors</u>	July 29, 2016

Dimiter Dimitrov	<u>10,550,179</u>	<u>Compositions and methods for treating cancer with anti-mesothelin immunotherapy</u>	January 18, 2019
John Schiller	<u>5,437,951</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	March 16, 1993
John Schiller	<u>5,618,536</u>	<u>Chimeric papillomavirus-like particles</u>	October 6, 1994
John Schiller	<u>5,674,835</u>	<u>Papillomaviral expression inhibitors</u>	June 6, 1995
John Schiller	<u>5,709,996</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>5,716,620</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>5,744,142</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>5,756,284</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>5,855,891</u>	<u>Chimeric papillomavirus-like particles</u>	January 9, 1997
John Schiller	<u>5,871,998</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>5,985,610</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 7, 1995
John Schiller	<u>6,599,739</u>	<u>Infectious papillomavirus pseudoviral particles</u>	March 30, 2000
John Schiller	<u>6,719,978</u>	<u>Virus-like particles for the induction of autoantibodies</u>	April 13, 2001
John Schiller	<u>7,220,419</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	February 21, 2003
John Schiller	<u>7,361,356</u>	<u>Self-assembling recombinant papillomavirus capsid proteins</u>	June 9, 2006
John Schiller	<u>7,371,572</u>	<u>Mouse titers after two immunizations with VLPs alone</u>	June 14, 2004
John Schiller	<u>7,462,356</u>	<u>Chimeric papillomavirus-like particles</u>	May 25, 2007
John Schiller	<u>7,479,280</u>	<u>Virus-like particles for the induction of autoantibodies</u>	May 1, 2006
John Schiller	<u>7,691,386</u>	<u>Chimeric papillomavirus-like particles</u>	December 9, 2008
John Schiller	<u>7,875,450</u>	<u>Virus-like particles for the induction of autoantibodies</u>	March 18, 2008
John Schiller	<u>8,394,411</u>	<u>Papillomavirus pseudoviruses for detection and therapy of tumors</u>	May 1, 2008

John Schiller	<u>8,404,244</u>	<u>Papillomavirus L2 N-terminal peptides for the induction of broadly cross-neutralizing antibodies</u>	February 1, 2006
John Schiller	<u>8,999,290</u>	<u>Papillomavirus pseudoviruses for detection and therapy of tumors</u>	February 8, 2013
John Schiller	<u>9,388,221</u>	<u>Papillomavirus L2 N-terminal peptides for the induction of broadly cross-neutralizing antibodies</u>	February 21, 2013
John Schiller	<u>10,117,947</u>	<u>Virus-like particle conjugates for diagnosis and treatment of tumors</u>	September 18, 2014
John Schiller	<u>10,188,751</u>	<u>Papillomavirus pseudoviruses for detection and therapy of tumors</u>	December 2, 2014
John Schiller	<u>10,279,019</u>	<u>PCSK9 peptide vaccine conjugated to a Qbeta carrier and methods of using the same</u>	February 11, 2015
Robert Kotin	<u>5,580,703</u>	<u>Human adeno-associated virus integration site DNA and uses thereof</u>	September 20, 1994
Robert Kotin	<u>5,693,531</u>	<u>Vector systems for the generation of adeno-associated virus particles</u>	November 24, 1993
Robert Kotin	<u>6,342,390</u>	<u>Lipid vesicles containing adeno-associated virus rep protein for transgene integration and gene therapy</u>	November 23, 1994
Robert Kotin	<u>6,468,524</u>	<u>AAV4 vector and uses thereof</u>	March 22, 2000
Robert Kotin	<u>6,723,551</u>	<u>Production of adeno-associated virus in insect cells</u>	August 13, 2002
Robert Kotin	<u>6,821,511</u>	<u>Methods of using adeno-associated virus rep protein</u>	August 3, 2001
Robert Kotin	<u>6,855,314</u>	<u>AAV5 vector for transducing brain cells and lung cells</u>	March 22, 2000
Robert Kotin	<u>6,984,517</u>	<u>AAV5 vector and uses thereof</u>	November 21, 2000
Robert Kotin	<u>7,271,002</u>	<u>Production of adeno-associated virus in insect cells</u>	November 8, 2002
Robert Kotin	<u>7,479,554</u>	<u>AAV5 nucleic acids</u>	July 19, 2005
Robert Kotin	<u>7,718,424</u>	<u>AAV4 vector and uses thereof</u>	November 20, 2003
Robert Kotin	<u>8,507,267</u>	<u>AAV4 vector and uses thereof</u>	March 8, 2010
Robert Kotin	<u>8,846,389</u>	<u>AAV4 vector and uses thereof</u>	July 2, 2013
Robert Kotin	<u>9,598,703</u>	<u>Capsid-free AAV vectors, compositions, and methods for vector production and gene delivery</u>	March 12, 2012



Robert Kotin	<u>10,335,466</u>	<u>AADC polynucleotides for the treatment of parkinson's disease</u>	November 5, 2015
Steven Rosenberg	<u>4,690,915</u>	<u>Adoptive immunotherapy as a treatment modality in humans</u>	August 8, 1985
Steven Rosenberg	<u>5,126,132</u>	<u>Tumor infiltrating lymphocytes as a treatment modality for human cancer</u>	August 21, 1989
Steven Rosenberg	<u>5,399,346</u>	<u>Gene therapy</u>	March 30, 1994
Steven Rosenberg	<u>5,578,275</u>	<u>In-line sampling with continuous flushing for friction sensitive liquid nitrate ester compositions</u>	February 16, 1995
Steven Rosenberg	<u>5,733,548</u>	<u>Immunogenic chimeras comprising nucleic acid sequences encoding endoplasmic reticulum signal sequence peptides and at least one other peptide, and their uses in vaccines and disease treatments</u>	June 5, 1995
Steven Rosenberg	<u>5,830,755</u>	<u>T-cell receptors and their use in therapeutic and diagnostic methods</u>	March 27, 1995
Steven Rosenberg	<u>5,831,016</u>	<u>Identification of TRP-2 as a human tumor antigen recognized by cytotoxic T lymphocytes</u>	October 4, 1996
Steven Rosenberg	<u>5,840,839</u>	<u>Alternative open reading frame DNA of a normal gene and a novel human cancer antigen encoded therein</u>	February 9, 1996
Steven Rosenberg	<u>5,843,648</u>	<u>P15 and tyrosinase melanoma antigens and their use in diagnostic and therapeutic methods</u>	January 10, 1995
Steven Rosenberg	<u>5,844,075</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	April 5, 1995
Steven Rosenberg	<u>5,846,540</u>	<u>Immunogenic chimeras comprising nucleic acid sequences encoding endoplasmic reticulum signal sequence peptides and at least one other peptide, and their uses in vaccines and disease treatments</u>	June 6, 1995
Steven Rosenberg	<u>5,856,187</u>	<u>Immunogenic chimeras comprising nucleic acid sequences encoding endoplasmic reticulum signal sequence peptides and at least one other peptide, and their uses in vaccines and disease treatments</u>	June 5, 1995

Steven Rosenberg	<u>5,874,560</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	April 22, 1994
Steven Rosenberg	<u>5,994,523</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	January 16, 1998
Steven Rosenberg	<u>6,083,703</u>	<u>Identification of TRP-2 as a human tumor antigen recognized by cytotoxic T lymphocytes</u>	September 28, 1998
Steven Rosenberg	<u>6,087,110</u>	<u>Alternative open reading frame DNA of a normal gene and a novel human cancer antigen encoded therein</u>	November 23, 1998
Steven Rosenberg	<u>6,132,980</u>	<u>Antibodies specific for TRP-2 a human tumor antigen recognized by cytotoxic T lymphocytes</u>	September 28, 1998
Steven Rosenberg	<u>6,187,306</u>	<u>Melanoma cell lines expressing shared immunodominant melanoma antigens and methods of using same</u>	August 5, 1997
Steven Rosenberg	<u>6,270,778</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	March 12, 1999
Steven Rosenberg	<u>6,537,560</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	May 5, 1998
Steven Rosenberg	<u>6,734,014</u>	<u>Methods and compositions for transforming dendritic cells and activating T cells</u>	January 7, 1999
Steven Rosenberg	<u>6,951,917</u>	<u>MHC-class II restricted melanoma antigens and their use in therapeutic methods</u>	September 26, 1995
Steven Rosenberg	<u>6,965,017</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	July 3, 2001
Steven Rosenberg	<u>7,001,600</u>	<u>Identification of TRP-2 as a human tumor antigen recognized by cytotoxic T lymphocytes</u>	August 30, 2000
Steven Rosenberg	<u>7,015,312</u>	<u>Antibodies to the protein product encoded by ORF3 of the TRP-1 gene and compositions and kits thereof</u>	May 16, 2000
Steven Rosenberg	<u>7,084,239</u>	<u>Cancer peptides of NY-ESO-1/CAG-3</u>	September 21, 1998
Steven Rosenberg	<u>7,232,887</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	October 15, 2003
Steven Rosenberg	<u>7,378,277</u>	<u>Methods and compositions for transforming dendritic cells and activating T cells</u>	June 26, 2003

Steven Rosenberg	<u>7,381,405</u>	<u>Methods of preparing lymphocytes that express interleukin-2 and their use in the treatment of cancer</u>	October 15, 2002
Steven Rosenberg	<u>7,419,957</u>	<u>Peptides of melanoma antigen and their use in diagnostic, prophylactic and therapeutic methods</u>	August 22, 2002
Steven Rosenberg	<u>7,476,535</u>	<u>TRP2 isoform TRP2-6b containing HLA-A2 restricted epitopes</u>	March 15, 2002
Steven Rosenberg	<u>7,501,501</u>	<u>MHC-Class II restricted melanoma antigens and their use in therapeutic methods</u>	October 8, 2004
Steven Rosenberg	<u>7,612,044</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	May 21, 2007
Steven Rosenberg	<u>7,619,057</u>	<u>MHC class II restricted T cell epitopes from the cancer antigen, NY ESO-1</u>	January 26, 2001
Steven Rosenberg	<u>7,723,111</u>	<u>Activated dual specificity lymphocytes and their methods of use</u>	March 9, 2001
Steven Rosenberg	<u>7,745,212</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	October 31, 2007
Steven Rosenberg	<u>7,749,719</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	October 31, 2007
Steven Rosenberg	<u>7,749,967</u>	<u>Peptides of a melanoma antigen and their use in diagnostic, prophylactic, and therapeutic methods</u>	August 21, 2008
Steven Rosenberg	<u>7,763,586</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	October 31, 2007
Steven Rosenberg	<u>7,803,614</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	October 31, 2007
Steven Rosenberg	<u>7,807,805</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	July 2, 2007
Steven Rosenberg	<u>7,915,036</u>	<u>Compositions comprising T cell receptors and methods of use thereof</u>	September 13, 2004
Steven Rosenberg	<u>7,998,736</u>	<u>Adoptive immunotherapy with enhanced T lymphocyte survival</u>	October 7, 2005
Steven Rosenberg	<u>8,030,280</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	August 6, 2010
Steven Rosenberg	<u>8,034,334</u>	<u>Immunotherapy with in vitro-selected antigen-specific lymphocytes after non-myeloablative lymphodepleting chemotherapy</u>	September 5, 2003

Steven Rosenberg	<u>8,088,379</u>	<u>Modified T cell receptors and related materials and methods</u>	September 26, 2007
Steven Rosenberg	<u>8,211,422</u>	<u>Chimeric receptor genes and cells transformed therewith</u>	October 24, 1995
Steven Rosenberg	<u>8,216,565</u>	<u>GP100-specific T cell receptors and related materials and methods of use</u>	January 11, 2008
Steven Rosenberg	<u>8,252,545</u>	<u>Peptides of a melanoma antigen and their use in diagnostic, prophylactic, and therapeutic methods</u>	May 19, 2010
Steven Rosenberg	<u>8,273,724</u>	<u>Melanoma antigens and their use in diagnostic and therapeutic methods</u>	July 28, 2011
Steven Rosenberg	<u>8,287,857</u>	<u>Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy</u>	July 8, 2011
Steven Rosenberg	<u>8,383,099</u>	<u>Adoptive cell therapy with young T cells</u>	August 26, 2010
Steven Rosenberg	<u>8,465,743</u>	<u>Anti-vascular endothelial growth factor receptor-2 chimeric antigen receptors and use of same for the treatment of cancer</u>	September 14, 2010
Steven Rosenberg	<u>8,556,882</u>	<u>Inducible interleukin-12</u>	April 22, 2010
Steven Rosenberg	<u>8,613,932</u>	<u>GP100-specific T cell receptors and related materials and methods of use</u>	May 30, 2012
Steven Rosenberg	<u>8,754,046</u>	<u>MHC class II restricted T cell epitopes from the cancer antigen, NY ESO-1</u>	September 28, 2009
Steven Rosenberg	<u>8,785,601</u>	<u>T cell receptors and related materials and methods of use</u>	January 25, 2010
Steven Rosenberg	<u>8,822,196</u>	<u>Anti-vascular endothelial growth factor receptor-2 chimeric antigen receptors and use of same for the treatment of cancer</u>	May 2, 2013
Steven Rosenberg	<u>9,074,185</u>	<u>Adoptive cell therapy with young T cells</u>	January 16, 2013
Steven Rosenberg	<u>9,128,080</u>	<u>Modified T cell receptors and related materials and methods</u>	November 28, 2011
Steven Rosenberg	<u>9,266,960</u>	<u>Anti-epidermal growth factor receptor variant III chimeric antigen receptors and use of same for the treatment of cancer</u>	March 21, 2012

Steven Rosenberg	<u>9,345,748</u>	<u>Anti-SSX-2 T cell receptors and related materials and methods of use</u>	September 14, 2011
Steven Rosenberg	<u>9,359,447</u>	<u>Anti-mesothelin chimeric antigen receptors</u>	March 5, 2013
Steven Rosenberg	<u>9,447,144</u>	<u>MHC class II restricted T cell epitopes from the cancer antigen, NY ESO-1</u>	May 22, 2014
Steven Rosenberg	<u>9,487,573</u>	<u>Murine anti-NY-ESO-1 T cell receptors</u>	May 22, 2013
Steven Rosenberg	<u>9,522,948</u>	<u>GP100-specific T cell receptors and related materials and methods of use</u>	December 13, 2013
Steven Rosenberg	<u>9,522,955</u>	<u>Anti-vascular endothelial growth factor receptor-2 chimeric antigen receptors and use of same for the treatment of cancer</u>	August 8, 2014
Steven Rosenberg	<u>9,624,306</u>	<u>Anti-epidermal growth factor receptor variant III chimeric antigen receptors and use of same for the treatment of cancer</u>	January 13, 2016
Steven Rosenberg	<u>9,688,739</u>	<u>T cell receptors and related materials and methods of use</u>	March 21, 2014
Steven Rosenberg	<u>9,822,162</u>	<u>Anti-human papillomavirus 16 E6 T cell receptors</u>	July 14, 2014
Steven Rosenberg	<u>9,844,569</u>	<u>Methods of producing enriched populations of tumor reactive T cells from peripheral blood</u>	April 30, 2013
Steven Rosenberg	<u>9,855,298</u>	<u>Methods of conditioning patients for T cell therapy</u>	May 27, 2016
Steven Rosenberg	<u>9,879,065</u>	<u>T cell receptors recognizing MHC class II-restricted MAGE-A3</u>	September 13, 2013
Steven Rosenberg	<u>10,087,230</u>	<u>Murine anti-NY-ESO-1 T cell receptors</u>	September 16, 2016
Steven Rosenberg	<u>10,143,724</u>	<u>Anti-SSX-2 T cell receptors and related materials and methods of use</u>	April 19, 2016
Steven Rosenberg	<u>10,166,255</u>	<u>Intracellular genomic transplant and methods of therapy</u>	July 29, 2016
Steven Rosenberg	<u>10,174,098</u>	<u>Anti-human papillomavirus 16 E7 T cell receptors</u>	May 29, 2015
Steven Rosenberg	<u>10,251,912</u>	<u>MHC class II restricted T cell epitopes from the cancer antigen, NY ESO-1</u>	August 19, 2016

Steven Rosenberg	<u>10,322,146</u>	<u>Methods of conditioning patients for T cell therapy</u>	July 13, 2017
Steven Rosenberg	<u>10,329,339</u>	<u>Anti-human papillomavirus 16 E6 T cell receptors</u>	October 18, 2017
Steven Rosenberg	<u>10,406,177</u>	<u>Modified cells and methods of therapy</u>	August 29, 2016
Steven Rosenberg	<u>10,407,485</u>	<u>Murine anti-NY-ESO-1 T cell receptors</u>	August 29, 2018
Steven Rosenberg	<u>10,544,392</u>	<u>Methods of isolating T cells and T cell receptors having antigenic specificity for a cancer-specific mutation from peripheral blood</u>	April 29, 2016
Steven Rosenberg	<u>10,556,940</u>	<u>T cell receptors recognizing HLA-Cw8 restricted mutated KRAS</u>	September 9, 2016
Steven Rosenberg	<u>RE39,788</u>	<u>Gene therapy</u>	November 4, 2003

## ANNEX 2

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates websites including [keionline.org](http://keionline.org) and [drugdatabase.info](http://drugdatabase.info) that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as [ip-health](http://ip-health.org), which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at [keionline.org](http://keionline.org).

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests in the open source database [drugdatabase.info](http://drugdatabase.info):

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/ni-h-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "[U.S. nixed India's plea on reforms in medicine](#)," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. [Front page](#).
- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," *Inside Views*, *IP-Watch.Org*.



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**From:** Bayha, Ryan (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D5A4353CD514322A8598DBB1751EE79-BAYHAR]  
**Sent:** 11/26/2019 11:57:16 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**Subject:** RE: Please send this correspondence to KEI

Ok.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, November 26, 2019 6:53 PM  
**To:** Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>  
**Cc:** Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>  
**Subject:** Please send this correspondence to KEI

Ryan:

Please send this reply to KEI via email on Wednesday morning at the address on the letter using the OSP email account.

Thanks,  
Mark

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health

REL0000025020

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**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 9/10/2019 9:22:42 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: "March-in"

Ok, she's seen those before at least and has a model on how to respond.

-----Original Message-----

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 10, 2019 4:54 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** "March-in"

Ann told me they just received two requests for March-in from KEI. As she explained it, sounds like requests for NIH to take title to inventions not properly reported to NIH. Not clear whether these are in fact Govt funded and it will be complicated to make any such determination.

Sent from my iPhone

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**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AaffA5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/10/2019 6:26:24 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]  
**Subject:** RE: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Of course I won't!!! Thanks!

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, October 8, 2019 2:53 PM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Cc:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>  
**Subject:** Re: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Don't answer

Sent from my iPhone

On Oct 8, 2019, at 2:38 PM, Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov> wrote:

**H – E – L – P !!!!!** Seems like a “war of attrition”. How do we end this dialogue once and forever?

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Tuesday, October 8, 2019 2:13 PM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** Re: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dr. Reichman,

Thank you for your response.

According to the OTT Website, Licensing FAQs (<https://www.ott.nih.gov/faqs/licensing-faqs#11>):

Q: How do I get an exclusive license?

A: While Government regulations reflect a preference for nonexclusive licenses, exclusive licenses are available when appropriate to promote successful commercial development of a licensed invention. . . . Upon receipt of an exclusive license application, the Technology Transfer Professional evaluates the license application using a number of criteria **to determine if an exclusive license is warranted** (see 37 CFR §404.7). **If the NIH determines an**

**exclusive license is warranted after review of the application a notice of intent to grant the license is published in the Federal Register** for a period of time . . . . During this time the public may object to the grant of the license. . . .

According to the above text, NIH technology transfer officers such as yourself determine whether to depart from the preference for a non-exclusive license and grant an exclusive license **before** the NIH publishes notice of the proposed license and invites public comment.

**How did you here determine that exclusivity was necessary and consistent with federal law and regulations governing licenses of government-owned technology?**

**Your** determination/reasoning regarding the applicable criteria is not confidential and is necessary for the public to be able to comment effectively on the prospective license.

Thank you,  
Kathryn

On Tue, Oct 8, 2019 at 1:29 PM Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)> wrote:

Kathryn,

The availability notice was first published in the FR on 10/20/2016!

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Monday, October 7, 2019 5:33 PM

**To:** Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)>

**Subject:** Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

As you know, Section 209(e) of the Bayh Dole Act guarantees the public's right to comment on a proposed exclusive patent license.

In relation to the licenses noticed at 84 FR 51171, you have:

- stated that the term of the licenses are to be decided;
- stated that the NIH's reasons for granting exclusivity are confidential;
- stated that the field of use listed is as broad as possible, because it is yet to be decided;

- stated that the NIH cannot tell us what other entities have applied for the license, because that information is confidential; and

- stated that how the NIH ensures that the licenses comply with the limitations governing scope is confidential.

If the terms of the license and how the NIH complies with the Bayh Dole Act are either undetermined or confidential or both, then what is the public's role in the notice and comment process guaranteed under Section 209?

Also, can you please state when the licensing opportunity notice E-241-2010 was first published?

Thank you,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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**From:** Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]  
**Sent:** 11/26/2019 1:07:02 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Ampey, Bryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9672b522d0b34f3792e2934dac636a57-ampeybc]  
**Subject:** RE: REVIEW BY WED: Proposed letter to KEI rejecting their admin appeal

Mark,

I think this is fine (albeit curt in tone!).

My only suggestion for revision is it constantly switches back and forth from referring to NIH as "we" and "our" to "it" and "it's". I would pick one and stick with it. Cheers, Carrie

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, November 25, 2019 8:13 PM  
**To:** Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>  
**Cc:** Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>  
**Subject:** Fwd: REVIEW BY WED: Proposed letter to KEI rejecting their admin appeal

Could you please review this response by Wed to KEI, already approved by OGC

Sent from my iPhone

Begin forwarded message:

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Date:** November 18, 2019 at 6:28:25 PM EST  
**To:** "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>  
**Cc:** "Koniges, Ursula (NIH/OD) [E]" <ursula.koniges@nih.gov>, "Ampey, Bryan (NIH/OD) [E]" <bryan.ampey@nih.gov>  
**Subject:** REIVEW SOON: Proposed letter to KEI rejecting their admin appeal

Carrie:

I mentioned in our 1:1 that this was coming down the track. Dale Berkley and I wrote it and NCI reviewed it. KEI submitted two requests for an administrative appeal of their objection to NCI licensing 2 cancer technologies. They mention a number of specific objections. This response addresses those objections and denies them standing for NIH to hear an appeal of their objections. The reference to "Ms" Love is correct because she is named as a co-objectitioner.

Regards,  
Mark  
Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer

REL0000025024



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**From:** Vathyam, Surekha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5ED61806C5BF4E9A819DDB37E91DEE70-VATHYAMS]  
**Sent:** 10/8/2019 12:55:27 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Burke, Andy (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305e280edc664e68939d4348603f56e6-burkear]  
**Subject:** RE: 10/7 TDT Forum on Exclusive Licensing of Federally-Owned Inventions  
**Attachments:** Exclusive Licensing Questions TDT Forum.pptx

Dear Mark, Dale and Andy,

Thank you all for a wonderfully informative discussion. It was a very well attended session with 30 in-person and about 70 WebEx participants. There is a lot of interest in getting access to the WebEx recording. I shared the WebEx recording file with the three of you just now on my One Drive folder and would like for you to let me know if any portions of this recording need to be deleted prior to uploading to the SharePoint site. It will be most helpful if you indicate the starting and ending minute of the recording that needs to be deleted. Also, it will be great if you can provide your input today as the level of enthusiasm for this is quite high especially among those who missed the meeting. We will also share the slide deck that Andy used with the questions (copy attached). Hope that will work for you. In time, perhaps we will transcribe responses and add them into the slide deck as an FAQ for the community. We would of course, run this by you before sharing.

Looking forward to your feedback on the WebEx recording if possible by COB today.

Regards,  
Surekha

**From:** Vathyam, Surekha (NIH/NCI) [E]  
**Sent:** Monday, October 7, 2019 10:26 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: 10/7 TDT Forum on Exclusive Licensing of Federally-Owned Inventions

Thanks, Mark. If you can also send your slides, it will be great.

Surekha

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, October 7, 2019 10:24 AM  
**To:** Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: 10/7 TDT Forum on Exclusive Licensing of Federally-Owned Inventions

**From:** Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>  
**Sent:** Monday, October 7, 2019 9:35 AM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Burke,



Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Subject:** RE: 10/7 TDTF Forum on Exclusive Licensing of Federally-Owned Inventions

Thanks for the bio, Dale. Yes, that would work. It might also be good for us to have a copy of the slides on our end in case we have unexpected technical difficulties in screen sharing (do not expect this to happen – but almost seems like it will happen as a consequence of my confidence 😊)

Surekha

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Monday, October 7, 2019 9:32 AM

**To:** Vathyam, Surekha (NIH/NCI) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Subject:** RE: 10/7 TDTF Forum on Exclusive Licensing of Federally-Owned Inventions

Surekha—attached is my bio, thanks. I expect that I can just share my screen with the group to show my slides, is that correct?

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

**From:** Vathyam, Surekha (NIH/NCI) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>

**Sent:** Friday, October 04, 2019 6:46 PM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Subject:** RE: 10/7 TDTF Forum on Exclusive Licensing of Federally-Owned Inventions

Dear Mark & Dale,

Attached is the final set of questions we received from the tech transfer community for the two of you. The attached version has a few more questions than the version Andy sent you on 10/2. I am hoping you will have slides to address these topics and that you will send them to me on Monday morning. Please share your bios with me by then as well. There is a tremendous amount of interest in this presentation in the community. Looking forward to a very robust TDTF forum on Monday. If you have any questions, please do not hesitate to reach out to me.

Regards,  
Surekha

**From:** Vathyam, Surekha (NIH/NCI) [E]

**Sent:** Monday, September 30, 2019 4:01 PM

**To:** Berkley, Dale (NIH/OD) [E] <[BerkleyD@OD.NIH.GOV](mailto:BerkleyD@OD.NIH.GOV)>; Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Subject:** 10/7 TDTF Forum on Exclusive Licensing of Federally-Owned Inventions

Dear Dale and Mark,

Thank you both for agreeing to present on aspects of exclusively licensing federally-owned inventions at the Monday, October 7<sup>th</sup> TDTF Forum (2-3:30pm) at NCI and via WebEx. I have enlisted the help of Andy Burke to act as a moderator so he can ask questions we receive from the community in advance of the forum to make sure we cover the topics of

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interest to the audience. I will be sending out an email to all asking that they send their questions to me and Andy so he can collate them and pass them along to you both by Friday (10/4) morning at the latest. It will be great if you can prepare slides that will be responsive to the topic each of you will be covering and send them to me by Monday (10/7) morning at the latest. I am listing below the title for your part of the presentation. Also, due to logistics, we will have Mark start the presentation followed by Dale. We could have questions happen organically as and when it makes sense to bring them up. I know the entire community will be looking forward to this presentation and discussion. As I mentioned, we plan to record the WebEx and we could edit out parts that either of you deem sensitive before uploading at our internal SharePoint site.

Please email me brief bios as soon as possible but no later than Friday (10/4).

I plan to put the following in the announcement for the 10/7 presentation and agenda:

Andrew R. Burke, Ph.D., Senior Technology Transfer Manager (NCI) will moderate a two-part presentation and discussion:

- a. In-person presentation and discussion, "NIH's response to comments received in response to exclusive license notices" by Dr. Mark L. Rohrbaugh, Ph.D., J.D., Special Advisor for Technology Transfer, Office of Science Policy, NIH.
- b. WebEx presentation and discussion, "Justification for granting exclusive licenses to Federally-owned inventions & introduction to antitrust laws" by Dale D. Berkley, Ph.D., J.D., Senior Attorney, HHS Office of General Council, PHD, NIH Branch.

Hope this will work for you all.

Regards,  
Surekha

# Exclusive Licensing Questions for Mark Rohrbaugh & Dale Berkley

TDTC Forum

7 October 2019

Moderated by Andy Burke

**b5**

**b5**

**b5**

**b5**

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**b5**

**b5**

**b5**

**b5**

**b5**

**b5**

**b5**

**b5**



**b5**

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**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 11/20/2019 9:51:58 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: HIV mAb license agreements

No, but ASF does.

KEI did not respond to the FRN.

Likely.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, November 20, 2019 4:49 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** RE: HIV mAb license agreements

Thanks. Congrats. Does HHS know? Did KEI object to the FedReg? Do you expect criticism?

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Wednesday, November 20, 2019 4:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Green, Wade (NIH/NIAID) [E] <wade.green@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** HIV mAb license agreements

Mark,

I write to confirm that the license agreement with GSK is in effect.

**b4,b5**

**b4,b5**

I have attached a briefing document for NIAID leadership that my team prepared; NIAID's communications director and her group are in this loop.

Note also that we recently received a draft release from ViiV, GSK's partner (for lack of a better term) in this effort. I have attached that draft, which includes comments from my team and from the Vaccine Research Center. NIAID's communication office (OCGR) is also in the loop on this.

Mike  
**Michael R. Mowatt, Ph.D.**  
Director, Technology Transfer and Intellectual Property Office

**National Institute of Allergy and Infectious Diseases**  
National Institutes of Health  
U.S. Department of Health and Human Services

+1 301 496 2644



National Institute of  
Allergy and  
Infectious Diseases

REL0000025029

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---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 9/10/2019 7:18:32 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 10, 2019 2:59 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Fwd: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

b5

Thoughts?

Sent from my iPhone

Begin forwarded message:

**From:** "Burke, Andy (NIH/NCI) [E]" <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Date:** September 10, 2019 at 2:20:25 PM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>, "Rodriguez, Richard (NIH/NCI) [E]" <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

**From:** Burke, Andy (NIH/NCI) [E]  
**Sent:** Tuesday, September 10, 2019 10:35 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Hi Mark and Richard,

A draft response to KEI's questions are provided for your review.

Thank you,

Andy

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Monday, September 9, 2019 12:30 PM  
**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Cc:** Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

REL0000025030

**Subject:** Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? **b5**
  - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
1. If the government has provided funding:
  - a. How much has been spent by the government on these trials? **b5**
  - b5**
  - b. Please identify any NIH grant numbers.
  - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. **b5**
- b5**
1. Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement
  - a. If you deny #4, please state the duration of exclusivity. **b5**
- b5**
1. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
2. According to the Federal Register notice, Intima Bioscience is "headquartered in New York." According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name "Intima Bioscience" using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name "Intima Capital" using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is "Intima Bioscience" or "Intima Capital." **b5**
3. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled "Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer"? **b5**  
**b5**
  - a. Was the exclusive license described in 80 FR 59790 executed? **b5**
  - b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
1. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? **b5**  
**b5**
2. Does Intima Bioscience has a website? If so, please provide a link to their website.  
**b5**
  - a. Note that "Intima Capital," a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
  - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in "Gene Engineering for Cancer Therapy" was funded by Intima Capital LLC.

- c. If Intima Capital and Intima Bioscience are related, what is the relationship?

**b5**

1. Please confirm whether the following CRADA is associated with the licensed technology:

**b5**

- a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer*
- b. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.

1. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"?

- a. If "Yes," please provide a citation for the listing(s).

**b5**

1. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this?

**b5**

**b5**

2. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology?

**b5**

Thank you in advance for your assistance in this matter.

Sincerely,  
Kathryn Ardizzone and Luis Gil Abinader

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**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 8/19/2020 7:22:15 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Thx. I'll call then.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, August 19, 2020 3:20 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** Re: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

4:30 works. b6

Sent from my iPhone

On Aug 19, 2020, at 3:04 PM, Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:

Hi Mark,

Can you spare a few minutes to chat about this today or tomorrow?

I'm available between 4:30 and 5 today, then again tomorrow before 10:30 and after 2.

I can call your mobile b6 or a different number if you prefer.

Thanks,

Mike

---

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Monday, August 17, 2020 8:37 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Hi Mark,

Checking back on this.

I'm out of town now and back on Wed.

Thanks,

REL0000025031

Mike  
Michael R. Mowatt, Ph.D.  
Director, Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
+1 301 496 2644

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**From:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Sent:** Wednesday, August 12, 2020 1:02:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Cc:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark and Surekha,

I reviewed the FRN (attached) and noticed that the comment period ended on 27 Jul, i.e., 3 days before the date of Mr. Love's letter (attached).

**b5**

Please let me know if you support this approach or if you recommend an alternative.

I will share the proposed communication with Jill Harper after we finalize our review.

Thanks,

Mike

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, August 4, 2020 4:06 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <[MMOWATT@niaid.nih.gov](mailto:MMOWATT@niaid.nih.gov)>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Alternatively,

**b5**

**b5**



**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, August 4, 2020 4:02 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

I don't recall [REDACTED] b5 I would suggest:

b5

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Tuesday, August 4, 2020 3:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark,

I've confirmed [REDACTED] b5  
I'll work with you to develop a draft response.

We agreed to: [REDACTED] b5  
[REDACTED] b5

Thanks,

Mike

**From:** Harper, Jill (NIH/NIAID) [E] <jharper@niaid.nih.gov>  
**Sent:** Thursday, July 30, 2020 8:39 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>  
**Cc:** Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Sullivan, Fantasia (NIH/NIAID) [C] <fantasia.sullivan@nih.gov>; Fowler, Karen (NIH/NIAID) [C] <fowlerk@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] <auchinclossh@niaid.nih.gov>  
**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mike and Surekha, please see below and attached, and let's discuss early next week.

Thanks,

Jill

---

**From:** "Fauci, Anthony (NIH/NIAID) [E]" <[afauci@niaid.nih.gov](mailto:afauci@niaid.nih.gov)>  
**Date:** Thursday, July 30, 2020 at 7:51:28 PM  
**To:** "Harper, Jill (NIH/NIAID) [E]" <[jharper@niaid.nih.gov](mailto:jharper@niaid.nih.gov)>  
**Cc:** "Conrad, Patricia (NIH/NIAID) [E]" <[conradpa@niaid.nih.gov](mailto:conradpa@niaid.nih.gov)>, "Barasch, Kimberly (NIH/NIAID) [C]" <[kimberly.barasch@nih.gov](mailto:kimberly.barasch@nih.gov)>  
**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Jill:

Please look into this and take care of it.

b5

Thanks,

Tony

**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Sent:** Thursday, July 30, 2020 11:59 AM  
**To:** Fauci, Anthony (NIH/NIAID) [E] <[AFAUCI@niaid.nih.gov](mailto:AFAUCI@niaid.nih.gov)>  
**Cc:** Paul Davis <[pdavisx@gmail.com](mailto:pdavisx@gmail.com)>; Sawyer, Eric <[ERICLSAWYER@gmail.com](mailto:ERICLSAWYER@gmail.com)>; Brook Baker <[b.baker@northeastern.edu](mailto:b.baker@northeastern.edu)>; Thiru Balasubramaniam <[thiru@keionline.org](mailto:thiru@keionline.org)>; Morten, Christopher <[christopher.morten@nyu.edu](mailto:christopher.morten@nyu.edu)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Peter Maybarduk <[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)>; lumbasia@citizen.org; Luis Villalon <[info@innovarte.cl](mailto:info@innovarte.cl)>; Merith Basey <[merith@essentialmedicine.org](mailto:merith@essentialmedicine.org)>; lpma75@gmail.com; Gopa Kumar <[kumargopakm@gmail.com](mailto:kumargopakm@gmail.com)>; Sangeeta <[sangeeta@twnetwork.org](mailto:sangeeta@twnetwork.org)>; Umunyana Rugege <[rugege@section27.org.za](mailto:rugege@section27.org.za)>; Ngqabutho Mpofu <[ngqabutho.mpofu@mail.tac.org.za](mailto:ngqabutho.mpofu@mail.tac.org.za)>; Manuel MARTIN <[Manuel.MARTIN@geneva.msf.org](mailto:Manuel.MARTIN@geneva.msf.org)>; Yuanqiong HU <[Yuanqiong.HU@geneva.msf.org](mailto:Yuanqiong.HU@geneva.msf.org)>  
**Subject:** Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Dr. Fauci,

Attached is a letter from several individuals and groups, asking that NIAID not grant exclusive rights in a HIV patent license for South Africa, India and other low income countries.

The license is to RNAceuticals, a firm without a web page. The technology is for N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains.

This letter addresses a narrow issue, the geographic scope of the license, and it asks that exclusivity does not extend to countries like South Africa and India, that have per capita incomes less than 30 percent of the United States.

Among the groups signing are the leading patient group for persons living with HIV in South Africa, where an estimated 19 percent of persons from 19 to 49 are living with HIV, and patient advocacy groups working in Southeast Asia, India, Brazil, Chile, Mexico, Ecuador, Argentina, Colombia, and Guatemala, as well as several US and globally based health groups and patient advocates.

Jamie

REL0000025031

--

James Love. Knowledge Ecology International

U.S. Mobile +1.202.361.3040

U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

<85 FR 41607 (2020-14836).pdf>

<Letter2Fauci.RNAceuticals.License.Geographic.Scope.30July2020.pdf>

<Love, J, et al. DRAFT 200812.docx>

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**From:** Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]  
**Sent:** 7/1/2020 5:25:57 PM  
**To:** OD-OSP [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6928d6a195334e79a9a4da63df9a522b-OD-OSP]  
**CC:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]  
**Subject:** Comments on article concerned about BARDA not "requiring" "reasonable pricing" of COVID vax  
**Attachments:** Some government Covid-19 contracts could skirt affordable pricing laws.pdf

OSPers:

I thought I would give a little perspective on this article, with the caveat that I know nothing about BARDA's use of OTA in particular circumstances. However, BARDA funds late stage development and production and has Other Transaction Authority (OTA) at its disposals for funding as it sees fit. OTA allows for funding award terms to be negotiated pretty much de novo as private parties would negotiate agreements. OTA does not require the use of standard grant terms or compliance with government FAR contract terms. Thus, there is no requirement to include Bayh-Dole provisions regarding new inventions and reserving the government right to March-In should the awardee not comply with statutory requirements (Some like KEI argue that the March-In authority allows the government to take away a company's exclusive patent rights and make a product generic should the company marketing a product relying on government funded patented invention not offer it at a "reasonable" price to consumers, but no government agency has ever interpreted the law that way).

**b5**

Just my 2 cents. Is that affordable?

Mark

**A new report finds the U.S. government awarded several drug makers contracts for Covid-19 research**

REL0000025032

**using agreements that would allow authorities to bypass laws that could ensure taxpayer-funded medicines or vaccines are affordable, STAT writes.** The contracts were all designated as so-called Other Transaction Agreements, which may have widespread implications for access to Covid-19 medical products. This is because these agreements may allow federal agencies to circumvent laws that could be used to safeguard drug pricing.

---

**From:** STAT Plus | Pharmalittle <[ed.silverman@statnews.com](mailto:ed.silverman@statnews.com)>

**Reply-To:** "[ed.silverman@statnews.com](mailto:ed.silverman@statnews.com)" <[ed.silverman@statnews.com](mailto:ed.silverman@statnews.com)>

**Date:** Wednesday, July 1, 2020 at 9:27 AM

**To:** Meredith Temple-O'Connor <[meredith.temple-o'connor@nih.gov](mailto:meredith.temple-o'connor@nih.gov)>

**Subject:** FDA sets Covid-19 vaccine guidance; White House grabs much of the remdesivir supply



**From:** Stackhouse, Thomas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7E1C23441B64258803CAB5E97DB8270-STACKHOT]  
**Sent:** 10/4/2019 2:42:20 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Portilla, Lili (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b03f548be224eb9b7b6167a32e9cc4a-portilll]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Ano, Susan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d6832e1b254404783859cf30cb352d2-anos]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Green, Wade (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fdd3b0456c40458e952e6c043b2a6b-williamswa]  
**Subject:** RE: KEI FOIA Requests

Checked with NCI FOIA and we are also working on a *no records* response.

b5

b5

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Friday, October 4, 2019 9:23 AM  
**To:** Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>; Stackhouse, Thomas (NIH/NCI) [E] <stackhot@otd.nci.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Green, Wade (NIH/NIAID) [E] <wade.green@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** RE: KEI FOIA Requests

Thanks, Lili.

NIAID's FOIA officer confirmed receipt of the request, indicating that NIAID plans a "no records" response and that

b5

b5

Mike

**From:** Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>  
**Sent:** Thursday, October 3, 2019 11:04 AM  
**To:** Stackhouse, Thomas (NIH/NCI) [E] <stackhot@otd.nci.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: KEI FOIA Requests

Hi Tom, Mike, Bruce, Sue and Mark:

FYEO, I wanted to make you all aware that NCATS IRP has received the following FOIA request from KEI. Have any of your ICs received a similar request?

Thanks,

Lili

REL0000025033

**From:** Gheen, Valery (NIH/NHLBI) [E] <gheenv@mail.nih.gov>  
**Sent:** Thursday, October 3, 2019 9:37 AM  
**To:** Seidel, Stephen (NIH/NCATS) [E] <seidels@mail.nih.gov>; Burgoon, Penny (NIH/NCATS) [E] <penny.burgoon@nih.gov>  
**Subject:** KEI FOIA Requests

Good morning Penny and Stephen -

Please see the attached KEI FOIA request. Most of the ICs received similar requests from KEI. The requester has clarified that she is seeking records specifically related to **Intramural** clinical trials. Please let me know if there is any NCATS-specific written guidance on the tracking of intramural clinical trial expenditures. In case it helps, I'm sharing the conclusion we reached for NHLBI below – we issued a “no records” response to their FOIA request. NINDS and NIAMS also responded with a similar no records response for the same reason as described below. If you have questions or if there is someone I should talk with directly at NCATS, please let me know. Thanks! - Val

Ms. Valery Gheen  
Deputy Chief, Freedom of Information and Privacy Act Branch  
FOIA Service Center  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
301-496-9737 FOIA line  
301-827-6254 direct line

**From:** Gheen, Valery (NIH/NHLBI) [E]  
**Sent:** Wednesday, October 2, 2019 1:41 PM  
**To:** Powers, Sarah (NIH/NHLBI) [E] <sarah.powers@nih.gov>  
**Subject:** RE: KEI FOIA Requests

How does this sound? The NHLBI Intramural Program searched its files and no records documenting procedures for tracking clinical trial budgets and expenses were located. Intramural clinical trial costs include many centralized processes and costs which are budgeted for and tracked separately by different offices throughout NIH, e.g., patient services at the CC, NIH personnel costs, etc.

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**From:** Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]  
**Sent:** 11/19/2019 7:20:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Exported BRAIN Record (Drug Pricing)  
**Attachments:** Exported BRAIN Record (Drug Pricing).docx



# Drug Pricing

SPECIAL TOPICSHOW HISTORY

Exported Date: Tue Nov 19 2019 14:19:22 GMT-0500 (Eastern Standard Time)

**b5**

**b5**

**b5**

**b5**

**b5**

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 9/10/2019 6:20:25 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrir]  
**Subject:** FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

**From:** Burke, Andy (NIH/NCI) [E]  
**Sent:** Tuesday, September 10, 2019 10:35 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Hi Mark and Richard,

A draft response to KEI's questions are provided for your review.

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, September 9, 2019 12:30 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>  
**Subject:** Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? b5
  - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
1. If the government has provided funding:
  - a. How much has been spent by the government on these trials? b5  
b5
  - b. Please identify any NIH grant numbers.
  - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated.  
b5
1. Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement

a. If you deny #4, please state the duration of exclusivity. **b5**  
**b5**

1. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
2. According to the Federal Register notice, Intima Bioscience is "headquartered in New York." According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name "Intima Bioscience" using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name "Intima Capital" using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is "Intima Bioscience" or "Intima Capital." **b5**

**b5**

3. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled "Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer"? **b5**
  - a. Was the exclusive license described in 80 FR 59790 executed? **b5**
  - b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?

1. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? **b5**

2. Does Intima Bioscience has a website? If so, please provide a link to their website. **b5**  
**b5**
  - a. Note that "Intima Capital," a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
  - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in "Gene Engineering for Cancer Therapy" was funded by Intima Capital LLC.
  - c. If Intima Capital and Intima Bioscience are related, what is the relationship? **b5**

**b5**

1. Please confirm whether the following CRADA is associated with the licensed technology: **b5**  
**b5**
  - a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer*
  - b. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.

1. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"?
  - a. If "Yes," please provide a citation for the listing(s). **b5**
1. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? **b5**

**b5**

2. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology?

**b5**

**b5**

Thank you in advance for your assistance in this matter.

Sincerely,  
Kathryn Ardizzone and Luis Gil Abinader



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**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 7/1/2020 1:50:34 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Federal government weakens its march-in rights

What's your take on this story from Axios? Unless BARDA is using "other transactional authorities," don't see how they could change the march in provisions in their contracts.

## 2. Federal government weakens its march-in rights

**The federal government has** watered down legal rights that could allow it to take over the rights of some potential coronavirus drugs, according to federal contracts obtained by consumer group Knowledge Ecology International and shared with Axios.

**The big picture:** The federal government has never used its so-called "march-in rights," but they're a theoretically powerful tool to intervene in cases where pharmaceutical companies charge high prices or don't produce enough of a product, Axios' Bob Herman reports.

**How it works:** Federal march-in rights, which have existed for 40 years, spell out four circumstances in which the government can take over the patents on drugs that were developed with federal funding, and license those patents to other companies.

**Those rights can kick in** if a patent holder doesn't make its medicines "available to the public on reasonable terms," known as "practical application."

- Three of those words — "on reasonable terms" — are "the legal basis for intervening in cases of unreasonable drug prices," said Kathryn Ardizzone, the lead attorney for Knowledge Ecology International, a progressive public interest group.

**But several companies** making coronavirus drugs and vaccines have deleted those words from contracts with the Biomedical Advanced Research and Development Authority (BARDA) which is part of the Department of Health and Human Services.

- Further, the contracts have deleted or narrowed the other circumstances in which march-in rights can be invoked, according to documents Knowledge Ecology International obtained through an open records request.

**HHS said in a statement** that the BARDA contracts "are focused on product development" and that when purchasing drugs, "one of the considerations in the price is any federal funding that was provided to develop the product."

**Go deeper:** You can read all of the federal documents obtained by KEI [here](#).

--

David White  
Keybridge Communications  
1722-A Wisconsin Ave. NW, Suite 21  
Washington, DC 20007  
202.471.4321  
[www.keybridgecommunications.com](http://www.keybridgecommunications.com)

*Like us on [Facebook](#). Follow us on [Twitter](#). And check out our [blog](#)!*

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 11/19/2019 3:05:35 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertson]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: Letter to KEI responding to admin appeals

Hi Mark,

Your statements regarding the Intima FR notice are accurate.

Thank you,

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, November 18, 2019 6:21 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Letter to KEI responding to admin appeals

Andy:

Can you give this a read through to check the statements about the license to Intima to be sure it is correct? Dale and I wrote it, and I already incorporated Dave's comments on the first technology. Note the reference to Ms. Love (not Mr. Love) because she is named as one of the objectors. My supervisor is reviewing it as well. When both are finished, it will be ready for me to send out.

Thanks  
Mark

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health

REL0000025039

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 9/10/2019 6:10:45 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: Questions Regarding Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy, 84 FR 45503

Hi Mark,

I sent you a longer set of questions and proposed answers this morning. I can resend, if needed. Let me know.

Thanks,

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 10, 2019 2:05 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: Questions Regarding Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy, 84 FR 45503

Fine with me. Are there other responses pending from you?

**From:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Sent:** Tuesday, September 10, 2019 2:02 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Questions Regarding Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy, 84 FR 45503

Hi Mark and Richard,

Further questions from KEI along with my proposed responses.

Please let me know if you have any questions or concerns.

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Tuesday, September 10, 2019 1:47 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>  
**Subject:** Questions Regarding Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy, 84 FR 45503

Dear Dr. Burke:

KEI looks forward to receiving your answers to the questions that we submitted to you regarding Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy, 84 FR 45503.

Please answer the following additional questions:

1. Will the license be a "start up license"? b5
2. Is NTC01174121, *Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Cancer*, associated with any of the licensed inventions? b5

b5

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 6/30/2020 3:55:05 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer (85 FR 36872)

Hi Mark,

I will revise my answers **b5** as you recommend. Regarding **b5**  
**b5**

**b5**

Finally, regarding the **b5**  
**b5**

Let me know if you have any remaining concerns.

Thank you,

Andy

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, June 30, 2020 9:38 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer (85 FR 36872)

Andy:

**b5**

**b5**

If

so, this is ok.

---

**From:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Sent:** Monday, June 29, 2020 5:07 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer (85 FR 36872)

REL0000025041



Hi Mark,

Draft responses to KEI provided below. Please let me know if you have any questions or concerns. Regarding question

**b5**

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Thursday, June 25, 2020 11:59 AM

**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Questions, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer (85 FR 36872)

Dear Dr. Burke:

Please answer the following questions regarding the Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer to Ziopharm Oncology, 85 FR 36872.

1. Has the NIH/NCI complied with its obligations to publicize the technologies as available for licensing?

**b5**

Where in the federal register did it do so?

**b5**

**b5**

2. Who invented the technologies? No licensing opportunity notice for the inventions is posted at [ott.nih.gov](http://ott.nih.gov), and the patent applications aren't published so if we have other way to obtain this information.

**b5**

3. Are there any publications describing the inventions?

**b5**

4. What grant numbers are associated with the inventions?

**b5**

5. How much did the NCI spend to develop the inventions?

**b5**

**b5**

6. Are there any clinical trials of the inventions? If so, what are their numbers?

**b5**

**b5**

7. How did NIH determine that exclusivity is a reasonable and necessary incentive?

**b5**

**b5**

8. How did NIH determine that the scope of the license is not broader than necessary?

**b5**

**b5**

9. What is the period of exclusivity?

**b5**

**b5**

10. Have/will NCI consider a period shorter than life of patent?

**b5**

Thank you in advance for your assistance with these questions, as part of the notice and comment period required by 35 U.S.C. 209(e).

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

REL0000025041

kathryn.ardizzone@keionline.org  
(202) 332-2670



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**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 8/19/2020 7:04:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries  
**Attachments:** 85 FR 41607 (2020-14836).pdf; Letter2Fauci.RNAceuticals.License.Geographic.Scope.30July2020.pdf; Love, J, et al. DRAFT 200812.docx

Hi Mark,

Can you spare a few minutes to chat about this today or tomorrow?

I'm available between 4:30 and 5 today, then again tomorrow before 10:30 and after 2.

I can call your mobile b5 or a different number if you prefer.

Thanks,

Mike

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Monday, August 17, 2020 8:37 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Hi Mark,

Checking back on this.

I'm out of town now and back on Wed.

Thanks,

Mike

Michael R. Mowatt, Ph.D.  
Director, Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
+1 301 496 2644

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REL0000025042

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**From:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>

**Sent:** Wednesday, August 12, 2020 1:02:53 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>

**Cc:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>

**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark and Surekha,

I reviewed the FRN (attached) and noticed that the comment period ended on 27 Jul, i.e., 3 days before the date of Mr. Love's letter (attached).

b5

Please let me know if you support this approach or if you recommend an alternative.

I will share the proposed communication with Jill Harper after we finalize our review.

Thanks,

Mike

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Sent:** Tuesday, August 4, 2020 4:06 PM

**To:** Mowatt, Michael (NIH/NIAID) [E] <[MMOWATT@niaid.nih.gov](mailto:MMOWATT@niaid.nih.gov)>

**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>

**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Alternatively

b5

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E]

**Sent:** Tuesday, August 4, 2020 4:02 PM

**To:** Mowatt, Michael (NIH/NIAID) [E] <[MMOWATT@niaid.nih.gov](mailto:MMOWATT@niaid.nih.gov)>

**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>

**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

I don't recall

b5

I would suggest:

b5

b5

**From:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>

**Sent:** Tuesday, August 4, 2020 3:40 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>; Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>

**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark,

I've confirmed [b5] I'll work with you to develop a draft response.

We agreed to [b5]

[b5]

Thanks,

Mike

**From:** Harper, Jill (NIH/NIAID) [E] <[jharper@niaid.nih.gov](mailto:jharper@niaid.nih.gov)>

**Sent:** Thursday, July 30, 2020 8:39 PM

**To:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>; Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>

**Cc:** Haskins, Melinda (NIH/NIAID) [E] <[haskinsm@mail.nih.gov](mailto:haskinsm@mail.nih.gov)>; Sullivan, Fantasia (NIH/NIAID) [C] <[fantasia.sullivan@nih.gov](mailto:fantasia.sullivan@nih.gov)>; Fowler, Karen (NIH/NIAID) [C] <[fowlerk@niaid.nih.gov](mailto:fowlerk@niaid.nih.gov)>; Auchincloss, Hugh (NIH/NIAID) [E] <[auchincloss@niaid.nih.gov](mailto:auchincloss@niaid.nih.gov)>

**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mike and Surekha, please see below and attached, and let's discuss early next week.

Thanks,

Jill

**From:** "Fauci, Anthony (NIH/NIAID) [E]" <[afauci@niaid.nih.gov](mailto:afauci@niaid.nih.gov)>

**Date:** Thursday, July 30, 2020 at 7:51:28 PM

**To:** "Harper, Jill (NIH/NIAID) [E]" <[jharper@niaid.nih.gov](mailto:jharper@niaid.nih.gov)>

**Cc:** "Conrad, Patricia (NIH/NIAID) [E]" <[conradpa@niaid.nih.gov](mailto:conradpa@niaid.nih.gov)>, "Barasch, Kimberly (NIH/NIAID) [C]" <[kimberly.barasch@nih.gov](mailto:kimberly.barasch@nih.gov)>

**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Jill:

Please look into this and take care of it.

[b5]

REL0000025042

Thanks,  
Tony

**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Sent:** Thursday, July 30, 2020 11:59 AM

**To:** Fauci, Anthony (NIH/NIAID) [E] <[AFAUCI@niaid.nih.gov](mailto:AFAUCI@niaid.nih.gov)>

**Cc:** Paul Davis <[pdavisx@gmail.com](mailto:pdavisx@gmail.com)>; Sawyer, Eric <[ERICLSAWYER@gmail.com](mailto:ERICLSAWYER@gmail.com)>; Brook Baker <[b.baker@northeastern.edu](mailto:b.baker@northeastern.edu)>; Thiru Balasubramaniam <[thiru@keionline.org](mailto:thiru@keionline.org)>; Morten, Christopher <[christopher.morten@nyu.edu](mailto:christopher.morten@nyu.edu)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Peter Maybarduk <[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)>; lumbasia@citizen.org; Luis Villalon <[info@innovarte.cl](mailto:info@innovarte.cl)>; Merith Basey <[merith@essentialmedicine.org](mailto:merith@essentialmedicine.org)>; lpma75@gmail.com; Gopa Kumar <[kumargopakm@gmail.com](mailto:kumargopakm@gmail.com)>; Sangeeta <[sangeeta@twnetwork.org](mailto:sangeeta@twnetwork.org)>; Umutyana Rugege <[rugege@section27.org.za](mailto:rugege@section27.org.za)>; Ngqabutho Mpofu <[ngqabutho.mpofu@mail.tac.org.za](mailto:ngqabutho.mpofu@mail.tac.org.za)>; Manuel MARTIN <[Manuel.MARTIN@geneva.msf.org](mailto:Manuel.MARTIN@geneva.msf.org)>; Yuanqiong HU <[Yuanqiong.HU@geneva.msf.org](mailto:Yuanqiong.HU@geneva.msf.org)>

**Subject:** Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Dr. Fauci,

Attached is a letter from several individuals and groups, asking that NIAID not grant exclusive rights in a HIV patent license for South Africa, India and other low income countries.

The license is to RNAceuticals, a firm without a web page. The technology is for N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains.

This letter addresses a narrow issue, the geographic scope of the license, and it asks that exclusivity does not extend to countries like South Africa and India, that have per capita incomes less than 30 percent of the United States.

Among the groups signing are the leading patient group for persons living with HIV in South Africa, where an estimated 19 percent of persons from 19 to 49 are living with HIV, and patient advocacy groups working in Southeast Asia, India, Brazil, Chile, Mexico, Ecuador, Argentina, Colombia, and Guatemala, as well as several US and globally based health groups and patient advocates.

Jamie

--

James Love. Knowledge Ecology International

U.S. Mobile +1.202.361.3040

U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

Dated: July 7, 2020.  
**Miguelina Perez,**  
*Program Analyst, Office of Federal Advisory  
Committee Policy.*  
[FR Doc. 2020-14948 Filed 7-9-20; 8:45 am]  
BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Neuropsychiatric Disorders and Review of PAR-19-289 Applications.

*Date:* August 4, 2020.

*Time:* 10:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, BDCN IRC, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular & Cellular Neurobiology.

*Date:* August 4, 2020.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [guthriep@csr.nih.gov](mailto:guthriep@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Glia.

*Date:* August 5, 2020.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).  
*Contact Person:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [guthriep@csr.nih.gov](mailto:guthriep@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 7, 2020.

**Miguelina Perez,**  
*Program Analyst, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2020-14950 Filed 7-9-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19) (R21, R01 Clinical Trials Not Allowed).

*Date:* July 30, 2020.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Bethesda, MD 20892-9834, (240) 669-5060, [james.snyder@nih.gov](mailto:james.snyder@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 2, 2020.

**Tyeshia M. Roberson,**  
*Program Analyst, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2020-14808 Filed 7-9-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Patent Commercialization License: N6, a Novel, Broad, Highly Potent HIV- Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains

AGENCY: National Institutes of Health.

ACTION: Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to RNAceuticals, Inc. located at 12 Indian Trail Road, Woodbridge, CT, USA to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, on or before July 27, 2020 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent commercialization license should be directed to: Chris Kornak, Lead Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852-9804, phone number 240-627-3705; Email: [chris.kornak@nih.gov](mailto:chris.kornak@nih.gov).

**SUPPLEMENTARY INFORMATION:** The following represents the intellectual property to be licensed under the prospective agreement.

N6: To date, NIAID has filed the following patent applications for this matter: Two U.S. Provisionals (E-131-

2015-0-US-01, 62/136,228, filed on 03/20/2015 and E-131-2015-1-US-01, 62/250,378 filed on 11/03/2015) that were combined into one PCT Application (E-131-2015-2-PCT-01, PCT/US2016/023145, filed on 03/18/2016), and entered the national stage in the United States (E-131-2015-2-US-07, 15/559,791, filed on 09/19/2017 and E-131-2015-2-US-09, 16/786,267, filed on 02/10/2020), Europe (E-131-2015-2-EP-05, 16716979.6 and E-131-2015-2-EP-10, 20156388.9), Canada (E-131-2015-2-CA-03, 2,980,005), Australia (E-131-2015-2-AU-02, 2016235541), China (E-131-2015-2-CN-04, 201680028822.8), South Africa (E-131-2015-2-ZA-08, 2017/06155), and India (E-131-2015-2-IN-06, 201737032671).

10E8: NIAID has filed the following patent applications for this matter, three U.S. Provisionals (E-253-2011-0-US-01, 61/556,660, filed on 11/07/2011, E-253-2011-1-US-01, 61/672,708, filed on 07/17/2012, and E-253-2011-2-US-01, 61/698,480, filed on 09/07/2012) that were combined into one PCT application (E-253-2011-3-PCT-01, PCT/US2012/063958, filed on 11/07/2012), and entered the national stage, in seven countries: United States (E-253-2011-3-US-05, 14/356,557, filed on 05/06/2014, E-253-2011-4-US-01, 14/450,773, filed on 08/04/2014, E-253-2011-3-US-09, 15/226,744, filed on 08/02/2016, E-253-2011-3-US-13, 15/699,902, filed on 09/08/2017), Europe (E-253-2011-3-EP-03, 12847241.2), China (E-253-2011-3-CN-02, 201280065580.1), India (E-253-2011-3-IN-04, 3678/DELNP/2014), South Africa (E-253-2011-3-ZA-06, 2014/03264), Brazil (E-253-2011-3-BR-07, BR112014010823-4), and Russia (E-253-2011-3-RU-08, 2014118462).

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide and the field of use may be limited to: (1) Administration to humans of DNA and/or RNA including without limitation modified RNA encoding a protein or proteins, containing all or some of the CDRs of N6 and (2) Administration to humans of DNA and/or RNA including without limitation modified RNA encoding a protein or proteins, containing all or some of the CDRs of 10E8.

The N6 antibody has evolved a unique mode of binding that depends less on a variable area of the HIV envelope known as the V5 region and focuses more on conserved regions, which change relatively little among HIV strains. This allows N6 to tolerate changes in the HIV envelope, including

the attachment of sugars in the V5 region, a major mechanism by which HIV develops resistance to other VRC01-class antibodies. N6 was shown in pre-clinical studies to neutralize approximately 98 percent of HIV isolates tested. The studies also demonstrate that N6 neutralizes approximately 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently. Its breadth and potency makes N6 a highly desirable candidate for development in therapeutic or prophylactic strategies. An abstract for this invention was published in the **Federal Register** on March 13, 2017.

The other invention, 10E8, has great potential to provide passive protection from infection, as a therapeutic, or as a tool for the development of vaccine immunogens. 10E8 is one of the most potent HIV-neutralizing antibodies isolated thus far and it can potentially neutralize up to 98% of genetically diverse HIV-1 strains. 10E8 is specific to the membrane-proximal external region (MPER) of the HIV envelope protein, GP41. An abstract for this invention was published in the **Federal Register** on April 24th, 2012 and June 24th, 2014.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent commercialization license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the

Freedom of Information Act, 5 U.S.C. 552.

**Surekha Vathiyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2020-14836 Filed 7-9-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2020-0002; Internal Agency Docket No. FEMA-B-2040]

### Changes in Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and

**b5**



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**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 11/18/2019 12:41:24 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: Please review and comment  
**Attachments:** Letter to KEI and Ms. Love 11-5-2019\_DL comments.docx

Good morning,

I had two minor corrections and one substantive comment/suggestion. Otherwise everything looks okay to me.

Oh, I see that the title of the file says "Ms. Love" but that should be "Mr. Love."

Dave

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, November 15, 2019 12:16 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Please review and comment

Dave:

Please review the response to KEI that Dale and I put together. After your review, my supervisor Carrie Wolinetz wants to give a quick look over and then I can send it.

Thanks,  
Mark

REL0000025043



Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health

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**b5**

**b5**

**b5**

**b5**



**b5**

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**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7Aaffa5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/3/2019 5:21:12 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, October 3, 2019 1:04 PM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

b5

**From:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Sent:** Thursday, October 3, 2019 11:50 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Mark,

What should I then do

b5

**From:** James Love <james.love@keionline.org>  
**Sent:** Thursday, October 3, 2019 11:27 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** kathryn ardizzone <kathryn.ardizzone@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Thank you Mark. In this case, we have asked for the names of other firms, if any, that have expressed interest in the inventions.

On Thu, Oct 3, 2019 at 4:49 PM Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

Jamie:

The first one is old language we have used for decades referencing the FOIA office's ability to make documents available for "public inspection". Public inspection means literally that, a place where one can physically inspect documents. It does not necessarily mean that documents are confidential because they are not available for public

REL0000025046

inspection. Comments and objections, other than those in the form of a completed license application will not be treated confidentially but they are not placed somewhere for public inspection.

Regards,

Mark

**From:** James Love <james.love@keionline.org>

**Sent:** Thursday, October 3, 2019 9:35 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>

**Cc:** kathryn ardizzone <kathryn.ardizzone@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>

**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

For a recent license, noticed today, October 3, 2019,

<https://www.federalregister.gov/documents/2019/10/03/2019-21520/prospective-grant-of-an-exclusive-patent-license-compositions-devices-and-processes-for-production>

The rule was that comments by third parties "may be made publicly available."

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

However, for your Sept 27, 2019, notice:

<https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>

You take the opposite position.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

How can you possibly claim objections to this license are confidential, while objections to others, some more recent even, are not confidential?

Is this an abuse of your discretion, or a misreading of the law by someone?

Jamie

On Wed, Oct 2, 2019 at 11:02 PM Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)> wrote:

Dear Kathryn,

Thanks for your inquiry. Please see my answers to your questions below. I hope I answered them in full.

Best regards,

Uri

Uri Reichman, Ph.D, MBA

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development (OTTAD)

NHLBI/NIH

Bethesda, MD

301-435-4616 (o)

**b6**

(m)

REL0000025046

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Wednesday, October 2, 2019 10:25 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>

**Cc:** James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>

**Subject:** Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

Early stage.

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

No!

3. How much has the NIH spent to support the development of the invention?

I do not have this information.

4. Is the period of exclusivity to be life of patent or less than life of patent?

It will be negotiated. Typically exclusive licenses are for the term of the patent.

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

It is determined on a case by case basis.

6. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

7. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

The license application is legally protected as confidential to the company.

8. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary? Confidential information from the license application is used to draft an appropriate field of use.
9. What criteria was used to select Generation Bio selected as licensee? 37 CFR 404 provides the criteria used by the agency to evaluate patent license application.
10. When did Generation Bio submit its license application? August 2019
11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not? No!
12. What diseases fall within the field of use for the exclusive license to Generation Bio?

This is the broadest possible scope. It will be negotiated with the company if the NIH moves forward with the license.

13. Please provide a list of other firms that expressed an interest in this license.

Applications are confidential.

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

James Love. Knowledge Ecology International

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]  
**Sent:** 9/6/2019 6:47:37 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

b5

Jim

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, September 6, 2019 2:43 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Subject:** RE: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

b5

**From:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Sent:** Friday, September 6, 2019 12:04 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Hi Mark,

What are your thoughts regarding KEI's request below? They want further information related to the clinical trials associated with the technology that is being licensed.

b5

Best,  
Jim

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Thursday, September 5, 2019 6:28 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Dr. Knabb:

Can you please confirm whether any of the following clinical trial numbers are associated with the license?

**NCT03448393**  
**NCT03241940**  
**NCT03233854**

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**NCT02315612.**

We need to know the phase, status, and patient enrollment numbers of any clinical trial associated with the technology because that information is related to the risks and development costs assumed by the prospective licensee, and thus the appropriate scope of the license.

The easiest way to provide us this information is to disclose the clinical trial number(s).

You mentioned, in your letter, that there is an active clinical trial associated with the first invention. Please: (1) disclose that trial number, (2) disclose any other trials associated with the technology, if any; and (3) let us know if any of the trial numbers listed above are associated with the technology.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.

**From:** Ano, Susan (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4D6832E1B254404783859CF30CB352D2-ANOS]  
**Sent:** 6/25/2020 3:30:46 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: GAO's questions to KEI about transparency of HHS intellectual property

b6 includes OTT (Karen, specifically) and the 8 ICs.

Best regards,

Sue

Susan Ano, Ph.D.  
Office of Technology Transfer  
The National Institute of Neurological Disorders and Stroke  
Physical location: 35A Convent Drive, Room GF333  
phone (301) 435-5515  
cell b6

"Prejudice is an emotional commitment to ignorance" - Dr. Nathan Rutstein

NIH Employee Assistance Program  
<https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/EAP/Pages/index.aspx>

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this email in error, please destroy the document and notify the sender of the error. Thank you.

-----Original Message-----

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, June 25, 2020 11:14 AM  
**To:** Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>  
**Subject:** RE: GAO's questions to KEI about transparency of HHS intellectual property

Is there a group email for them?

-----Original Message-----

**From:** Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>  
**Sent:** Thursday, June 25, 2020 11:01 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: GAO's questions to KEI about transparency of HHS intellectual property

Thanks, Mark. Should this go to the other independent tech transfer ICs (NIMH, NIDDK, and NHLBI)?

Best regards,

Sue

Susan Ano, Ph.D.  
Office of Technology Transfer  
The National Institute of Neurological Disorders and Stroke Physical location: 35A Convent Drive, Room GF333 phone (301) 435-5515 cell b6

"Prejudice is an emotional commitment to ignorance" - Dr. Nathan Rutstein

NIH Employee Assistance Program  
<https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/EAP/Pages/index.aspx>

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this email in error, please destroy the document and notify the sender of the error. Thank you.

REL0000025049

-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
Sent: Thursday, June 25, 2020 10:36 AM  
To: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Brown, Tiffany (NIH/OD/OMA) [E] <brownty1@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Driscoll, Claire (NIH/NHGRI) [E] <cdriscol@mail.nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>; Stackhouse, Thomas (NIH/NCI) [E] <stackhot@otd.nci.nih.gov>  
Subject: FW: GAO's questions to KEI about transparency of HHS intellectual property

FYI

-----Original Message-----

From: Joe Allen <jallen@allen-assoc.com>  
Sent: Thursday, June 25, 2020 9:46 AM  
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
Subject: GAO's questions to KEI about transparency of HHS intellectual property  
Importance: High

this response to GAO on the KEI website.  
(<https://www.keionline.org/wp-content/uploads/KEI-response-to-four-GAO-questions-June-22-2020.pdf>)

Apparently, GAO asked KEI to respond to 4 questions.

--

Joseph P. Allen  
President  
Allen and Associates  
60704 Rt. 26, South  
Bethesda, OH 43719  
(W) 740-484-1814  
(C) [REDACTED] b6  
[www.allen-assoc.com](http://www.allen-assoc.com)

---

**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AaffA5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/3/2019 5:20:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

OK, thanks!

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, October 3, 2019 1:03 PM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

I will but not right away

**From:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Sent:** Thursday, October 3, 2019 11:47 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Hi Mark,

Can you respond to this one?

Thanks,

Uri

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Thursday, October 3, 2019 10:17 AM  
**To:** James Love <james.love@keionline.org>  
**Cc:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dr. Reichman,

In addition to Jamie's comments, I would add that under a plain reading of the relevant federal regulations, only one component of a license application must be treated as confidential - the applicant's development plan. Other aspects of the plan are not confidential.

**37 CFR § 404.14, Confidentiality of information**, clearly states that "any **plan** submitted pursuant to **§ 404.8(h)** and any report required by **§ 404.5(b)(6)** shall be treated as commercial or financial information obtained from a person and privileged and confidential[.]"

**§ 404.8(h), Application for a license**, lists 11 different components of a license application. Only one of those components - 404.8(h)(a)(8) - refers to a **plan**. Thus, under any straightforward reading of 37 CFR § 404.14 and § 404.8(h), the only confidential aspect of a license application is the plan described at 404.8(h)(a)(8). If the drafters of the regulation intended to include *all components* of a license application, they could have easily written 37 CFR § 404.14 to state that "any **license application** submitted pursuant to § 404.8(h) shall be treated as confidential." They did not. At the risk of sounding repetitive, § 404.14 was explicitly limited to plans. So, for example, the identity of an applicant 404.8(h)(a)(3) is not made confidential under 37 CFR § 404.14.

NIH has an obligation to abide by the law as it is written. Please explain how, in the NIH's view, 37 CFR § 404.14 and § 404.8(h) could be interpreted other than how I have just laid out.

Sincerely,  
Kathryn Ardizzone

On Thu, Oct 3, 2019 at 9:35 AM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:

For a recent license, noticed today, October 3, 2019,  
<https://www.federalregister.gov/documents/2019/10/03/2019-21520/prospective-grant-of-an-exclusive-patent-license-compositions-devices-and-processes-for-production>

The rule was that comments by third parties "may be made publicly available."

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

However, for your Sept 27, 2019, notice:

<https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>

You take the opposite position.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

How can you possibly claim objections to this license are confidential, while objections to others, some more recent even, are not confidential?

Is this an abuse of your discretion, or a misreading of the law by someone?

Jamie

On Wed, Oct 2, 2019 at 11:02 PM Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)> wrote:

Dear Kathryn,

Thanks for your inquiry. Please see my answers to your questions below. I hope I answered them in full.

REL0000025050

Best regards,

Uri

Uri Reichman, Ph.D, MBA

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development (OTTAD)

NHLBI/NIH

Bethesda, MD

301-435-4616 (o)

443-938-0972 (m)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Wednesday, October 2, 2019 10:25 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>

**Subject:** Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

Early stage.

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?



No!

3. How much has the NIH spent to support the development of the invention?

I do not have this information.

4. Is the period of exclusivity to be life of patent or less than life of patent?

It will be negotiated. Typically exclusive licenses are for the term of the patent.

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

It is determined on a case by case basis.

6. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

7. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

The license application is legally protected as confidential to the company.

8. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary? Confidential information from the license application is used to draft an appropriate field of use.

9. What criteria was used to select Generation Bio selected as licensee? 37 CFR 404 provides the criteria used by the agency to evaluate patent license application.

10. When did Generation Bio submit its license application? August 2019

11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not? No!

12. What diseases fall within the field of use for the exclusive license to Generation Bio?

This is the broadest possible scope. It will be negotiated with the company if the NIH moves forward with the license.

13. Please provide a list of other firms that expressed an interest in this license.

Applications are confidential.

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.

REL0000025050

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

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--

James Love. Knowledge Ecology International

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670



**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 2/18/2020 6:42:02 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Green, Wade (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fdd3b0456c40458e952e6c043b2a6b-williamswa]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** RE: Responses to KEI

Thanks, Mark. Will do.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, February 14, 2020 6:36 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Green, Wade (NIH/NIAID) [E] <wade.green@nih.gov>  
**Subject:** RE: Responses to KEI

1.  
2.  
3.  
4.

b5

I recommend:

b5

b5

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Friday, February 14, 2020 5:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Green, Wade (NIH/NIAID) [E] <wade.green@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** Responses to KEI

Mark and Dale,

I believe my staff has consulted you about NIAID's response to KEI's inquiry regarding a FRN we published in January. The draft response is attached.

I'm writing to confirm a few points:

b5

Thanks for your ongoing guidance and support.

REL0000025051

I hope you enjoy a restful weekend.

Mike

**Michael R. Mowatt, Ph.D.**

Director, Technology Transfer and Intellectual Property Office

**National Institute of Allergy and Infectious Diseases**

National Institutes of Health

U.S. Department of Health and Human Services

+1 301 496 2644



National Institute of  
Allergy and  
Infectious Diseases

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REL0000025051

**From:** Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]  
**Sent:** 6/24/2020 5:29:42 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: KEI comments for A-462-2019 and A-273-2020

Hi Mark,

b5

I have not yet sent the word document response that I provide, I'd happily modify the response to KEI prior to sending.

Best,  
Jim

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, June 24, 2020 12:40 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: KEI comments for A-462-2019 and A-273-2020

Sorry I misread the email. Jim,

b5

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, June 24, 2020 12:36 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: KEI comments for A-462-2019 and A-273-2020

Thanks Jim. Could you and Richard

b5

b5

**From:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Sent:** Wednesday, June 24, 2020 12:18 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** KEI comments for A-462-2019 and A-273-2020

Re: KEI comments for A-462-2019 (Senti Bio) and A-237-2020 (Vor Bio)  
NIH Technology: E-097-2018  
FRN publication: *Federal Register* Vol. 85, No. 94, pages 28966-28967

Hi Mark,

REL0000025054

Attached are comments from KEI for the above referenced proposed exclusive licenses, a proposed response, and the emails that I received from KEI. Happy to discuss after you've had a chance to review.

Jim

---

**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 2/14/2020 10:39:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkeleyd]  
**CC:** Green, Wade (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fdd3b0456c40458e952e6c043b2a6b-williamswa]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** Responses to KEI  
**Attachments:** KEI response letter- TeralImmune license-Feb 11.docx

Mark and Dale,

I believe my staff has consulted you about NIAID's response to KEI's inquiry regarding a FRN we published in January. The draft response is attached.

I'm writing to confirm a few points:

**b5**

Thanks for your ongoing guidance and support.

I hope you enjoy a restful weekend.

Mike  
**Michael R. Mowatt, Ph.D.**  
Director, Technology Transfer and Intellectual Property Office

**National Institute of Allergy and Infectious Diseases**  
National Institutes of Health  
U.S. Department of Health and Human Services

+1 301 496 2644



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REL0000025056



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NIAID

5601 Fishers Lane  
Rockville, MD 20852  
Suite 6D, MSC 9804  
Tel (301) 496-2644

**b5**

---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 11/15/2019 4:39:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Rydapt  
**Attachments:** Summary of Rydapt Review 11152019ah.docx; SUMMARY OF NIH REVIEW OF RYDAPT 12132018 07242019 08272019 ah-mfd 09252019 (002).docx

Mark:

I have been asked to summarize my office's review of the KEI Rydapt request as well as OPERA's response based on the directions I was given. The attached is a draft and I will be adding more dates, etc. Since you participated in the review of this KEI request, can you review the attached summary. I have also attached the summary of DEITR's review that includes your review and b4,b5 Could you also review the attached and make any edits or clarifications that are necessary.

Thanks.

Ann

Ann M. Hammersla, J.D.  
Director, Division of Extramural Inventions  
and Technology Resources  
Office of Policy for Extramural Research Administration

**Summary  
of the Analysis of  
Knowledge Ecology International's  
March 21, 2018 Request**

**1. Knowledge Ecology International's (KEI) March 21, 2018 request:**

- a. Request included 5 attachments that described 2 patents granted to Dr. James Griffin and assigned to the Dana-Farber Cancer Institute.
- b. Two U.S. Patents 7,973,031 and 8,222,244 (Patents) did not state e.g. did not include the government support clause in the issued patents that the underlying inventions were funded with NIH funding.
- c. Patents are listed in the Food and Drug Administration's (FDA) Orange Book as being used in the commercialization of the drug Rydapt®.
- d. KEI's request provides information about the pricing of Rydapt® and stated that "the high cost is a barrier to access and a fiscal strain on health systems."
- e. KEI's request provides background information about Dr. James Griffin, what Rydapt® does, a statement from the FDA, information about the other patents included in the FDA's Orange Book for the manufacture of Rydapt®, statements of Dr. Griffin's NCI's, NIDDK, and NHLBI support from 1985-2012.
- f. One attachment outlines "Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions" and includes remedies for non-disclosure of government funding which KEI states actions could be taken to:
  - i. Non-disclosure permits the federal government to receive title to the invention (35 U.S.C. §202(c)(1), 37 C.F.R. §401.14(a))
  - ii. Correction of the Patent will establish other enforceable rights for the federal government
    1. Requirement to manufacture substantially in the U.S. (35 U.S.C. §204)
    2. "Government rights in a subject invention also implicates the requirement repeated in numerous sections of the Bayh-Dole Act that there be "practical application" of the invention, including once in 35 U.S.C. §203 on march-in rights...."
    3. 35 U.S.C. §203(a) – "the government may require the grant of a license to a third party, or may grant such a license itself, if any of the four conditions are met, including the obligation of practical application...."
    4. "The government also retains a perpetual non-exclusive royalty-free license in the invention written into any funding agreement under 35 U.S.C. §202(c)(4)...."
- g. One attachment contained a report from Research Portfolio Online Reporting Tools (RePort) of all of Dr. Griffin's NIH funding.
- h. Page 11 of 12 of KEI's attachment "Rydapt (INN midostaurin) – Failures to disclose government funding for patents granted to James Griffin and assigned to Dana-Farber Cancer Institute in the FDA Orange Book" in Section "Requested Remedies for Non-disclosure" state:
  - i. Paragraph 1: "The Bayh-Dole Act and federal regulations and guidelines obligate contractors to disclose government rights in subject inventions...."



- ii. Paragraph 2: "After establishing a failure by the patent holder to disclose the federal funding, an agency may choose to require the patent holders to provide a disclose to iEdison and submit a Certificate of Correction to the United States Patent and Trademark (USPTO)...."
- iii. Paragraph 3: The disclosure itself is an acknowledgement that the federal government has certain rights in the patents, and the patent holder has certain obligations...."
- iv. Paragraphs 4 and 5 (Specific KEI Request):

The failure to make a timely disclosure of the federal funding should be seen as an attempt to evade these responsibilities and as a denial of the government's rights in the invention.

KEI recommends that the federal government take title to the invention, since the lesser remedy of requiring late disclosure has not, in the past, provided an adequate incentive for patent holders to comply with the disclosure obligations.

- i. See Attachments 1 for KEI's March 21, 2018 request.

**b4,b5**

**b5**

**b4,b5**

**5. KEI's Objections to the NIH Response it received by email on November 14, 2019:**

- a. KEI's objections are: (1) that it did not ask for NIH to march-in and (2) that its request by citing Bayh-Dole in its cover page and in several other places in its request, KEI's specific requested NIH to take title because of non-disclosure to NIH of the 2 patents in question.

**b5**

## SUMMARY OF NIH REVIEW OF RYDAPT

**b4,b5**

**b4,b5**

AH 12/13/2018 rev. 09/25/2019

REL0000025057.0002

**b4,b5**

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**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 11/15/2019 2:45:43 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: See comments in the attached letter to KEI

Great comments, thanks. I've lost track who else should look at this and approve (Dave Lambertson). Can you take it from here?

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, November 14, 2019 6:13 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** See comments in the attached letter to KEI

Happy to discuss.

Thanks,  
Mark

REL0000025059

---

**From:** Portilla, Lili (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9B03F548BE224EB9B7B6167A32E9CC4A-PORTILL] [E]  
**Sent:** 10/3/2019 3:03:52 PM  
**To:** Stackhouse, Thomas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7e1c23441b64258803cab5e97db8270-stackhot]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Ano, Susan (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d6832e1b254404783859cf30cb352d2-anos]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: KEI FOIA Requests  
**Attachments:** KEI FOIA Request to NCATS re Budget Record Keeping Procedures.pdf

Hi Tom, Mike, Bruce, Sue and Mark:

FYEO, I wanted to make you all aware that NCATS IRP has received the following FOIA request from KEI. Have any of your ICs received a similar request?

Thanks,

Lili

**From:** Gheen, Valery (NIH/NHLBI) [E] <[gheenv@mail.nih.gov](mailto:gheenv@mail.nih.gov)>  
**Sent:** Thursday, October 3, 2019 9:37 AM  
**To:** Seidel, Stephen (NIH/NCATS) [E] <[seidels@mail.nih.gov](mailto:seidels@mail.nih.gov)>; Burgoon, Penny (NIH/NCATS) [E] <[penny.burgoon@nih.gov](mailto:penny.burgoon@nih.gov)>  
**Subject:** KEI FOIA Requests

Good morning Penny and Stephen -

Please see the attached KEI FOIA request. Most of the ICs received similar requests from KEI. The requester has clarified that she is seeking records specifically related to ***Intramural*** clinical trials. Please let me know if there is any NCATS-specific written guidance on the tracking of intramural clinical trial expenditures. In case it helps, I'm sharing the conclusion we reached for NHLBI below – we issued a “no records” response to their FOIA request. NINDS and NIAMS also responded with a similar no records response for the same reason as described below. If you have questions or if there is someone I should talk with directly at NCATS, please let me know. Thanks! - Val

Ms. Valery Gheen  
Deputy Chief, Freedom of Information and Privacy Act Branch  
FOIA Service Center  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
301-496-9737 FOIA line  
301-827-6254 direct line

**From:** Gheen, Valery (NIH/NHLBI) [E]  
**Sent:** Wednesday, October 2, 2019 1:41 PM

REL0000025060



To: Powers, Sarah (NIH/NHLBI) [E] <[sarah.powers@nih.gov](mailto:sarah.powers@nih.gov)>

Subject: RE: KEI FOIA Requests

How does this sound?

b5

**b5**



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

September 26, 2019

Marianne Manheim  
FOIA and Privacy Act Coordinator  
National Center for Advancing Translational Sciences  
Via NIH Online FOIA Portal

**Re: Freedom of Information Act Request**

Dear Ms. Manheim:

Under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, Knowledge Ecology International (KEI) requests all documents referring to the National Center for Advancing Translational Sciences (NCATS)'s procedures for maintaining records of budgets and/or expenses associated with NCATS clinical trials.

**Request for Full Waiver of Fees**

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) and 45 C.F.R. § 5.45(a), which stipulate that FOIA fees must be waived where disclosure "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government" and "is not primarily in the commercial interest of the requester."

Under Department of Health and Human Services regulations, NCATS "must furnish records responsive to a request without charge or at a reduced rate when . . . the following three factors are satisfied:

- (1) Disclosure of the requested information would shed light on the operations or activities of the government[;]
- (2) Disclosure of the requested information would be likely to contribute significantly to the public understanding of those operations or activities[; and]
- (3) The disclosure [is] not [] primarily in the commercial interest of the requester[.]"

45 C.F.R. § 5.45(b).

1. Disclosure of the requested information would shed light on the operations or activities of the NCATS.

This request pertains to government operations or activities because it seeks the NCATS's procedures for maintaining records of the budgets and expenditures associated with clinical trials conducted or sponsored by NCATS.

2. Disclosure of the requested information is likely to contribute significantly to public understanding of the federal government's contribution to biomedical research.

The records sought in this request will enable KEI to shape FOIA requests for NCATS clinical trial costs, which will allow KEI to contribute significantly to the public's understanding of the government's contribution to biomedical research.

KEI intends to study the costs of NCATS clinical trials, particularly for new cell and gene therapies, in order to determine how much it costs to manufacture those technologies and bring them to market, and how much the federal government has contributed to their discovery.

Relatively little is known about the cost of manufacturing cell and gene therapies and the federal government's contribution to their development, in part due to the asymmetry of information between the public and private research institutions and pharmaceutical companies, as well as the newness of the technologies.

The requested materials will help advance the public's understanding of the subject. The NCATS likely has conducted intramural clinical trials that helped develop new cell and gene therapies and thus likely possesses records pertaining to the cost to manufacture and research them.

The records requested by KEI are not publicly available. While the NIH publishes information about its extramural grant application and reporting process online, its website apparently does not disclose all NCATS recordkeeping procedures pertaining to NCATS clinical trials.

KEI has the proven ability to disseminate its analysis of the disclosed records to the public. KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *STAT News* and in several academic and policy journals. For more information about KEI's ability to disseminate information, including its analysis of FOIA records, to the public, see Annex 1.

3. Disclosure is not primarily in the commercial interest of KEI.

The request is not in KEI's commercial interest. KEI is a nonprofit, 501(c)(3) public interest organization, and distributes its analysis to the public free of charge. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. *See Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

**Additional Comments**

Please provide the documents requested in electronic format.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org).

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone  
Knowledge Ecology International  
1621 Connecticut Ave NW Suite 500  
Washington, DC 20009  
(202) 332-2670  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

Claire Cassedy  
Knowledge Ecology International  
1621 Connecticut Ave NW Suite 500  
Washington, DC 20009  
(202) 332-2670  
[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)

## ANNEX 1

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates websites including [keionline.org](http://keionline.org) and [drugdatabase.info](http://drugdatabase.info) that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as [ip-health](http://ip-health), which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at [keionline.org](http://keionline.org).

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs";
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec";
- 2017 March 1. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB"; and
- 2015 June 18. "FOIA regarding General Electric's lobbying of USTR to oppose WIPO Treaty for the Blind".

The following are examples of KEI's use of data from FOIA requests in the open source database [drugdatabase.info](http://drugdatabase.info):

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/nih-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "[U.S. nixed India's plea on reforms in medicine](#)," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. [Front page](#).
- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *Stat News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen 't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med*. (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," *Inside Views, IP-Watch.Org*.

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**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 11/15/2019 11:57:23 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: KEI/Rydapt Issue  
**Attachments:** AnnHammersla-Rydapt-20March2018.pdf; Rydapt-james-griffin-dana-farber-novartis-21Mar2018 (002).pdf; SUMMARY OF NIH REVIEW OF RYDAPT 12132018 07242019 08272019 ah-mfd 09252019.docx; FW: Follow- Up RE: 1:1 Briefing Ann; Rydapt - Dana Farber; FW: Rydapt - failure to disclose federal funding

**From:** Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>  
**Sent:** Thursday, November 14, 2019 5:47 PM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Cc:** Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>  
**Subject:** KEI/Rydapt Issue

Hi Ann,

Michelle needs an analysis of the KEI/Rydapt issue:

b5

b5

b5

Please provide to Michelle before the two of you discuss.

Thanks,

Kristin

**SUMMARY OF NIH REVIEW OF RYDAPT**

**b4,b5**



**b4,b5**

AH 12/13/2018 rev. 09/25/2019

REL0000025061.0003

**b4,b5**

July 24, 2019 and August 27, 2019

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**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 10/25/2019 10:23:34 AM  
**To:** Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]  
**CC:** hamemrslaa@nih.gov  
**Subject:** FW: Follow- Up RE: 1:1 Briefing Ann; Rydapt - Dana Farber  
**Attachments:** DRAFT NIH Determination Response to KEI 10242019ah.docx; SUMMARY OF NIH REVIEW OF RYDAPT 12132018 07242019 08272019 ah-mfd 09252019.docx

Kristin: I added a background document that may be helpful. It does summarize the PO's review [b4,b5]  
[b4,b5] I also deleted [b5] the original draft letter and replaced it with [b5]

Please let me know if more information is needed.

Thanks.

Ann

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**From:** Hammersla, Ann (NIH/OD) [E]  
**Sent:** Thursday, October 24, 2019 2:46 PM  
**To:** Ta, Kristin (NIH/OD) [E] <Kristin.Ta@nih.gov>  
**Cc:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** RE: Follow- Up RE: 1:1 Briefing Ann; Rydapt - Dana Farber

Kristin:

Thank you for sending me the letter that was sent to Dana Farber.

I have attached my draft responding to the KEI request to take title to two inventions based on non-disclosure to NIH. I have also included a couple of sentences for background information of the KEI request. [b5]

[b5]

I recommend that [b5]  
[b5]

Ann

---

**From:** Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>  
**Sent:** Thursday, October 24, 2019 2:29 PM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** RE: Follow- Up RE: 1:1 Briefing Ann

Hi Ann,

Michelle asked me to follow-up with you by today, so while she didn't give a deadline I think it would be good to have it by tomorrow or Monday so that she can review before meeting with Jodi later in the week. Attaching b4

b4 for your reference.

Thanks!

Kristin

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**From:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>

**Sent:** Thursday, October 24, 2019 1:49 PM

**To:** Ta, Kristin (NIH/OD) [E] <[kristin.ta@nih.gov](mailto:kristin.ta@nih.gov)>

**Subject:** RE: Follow- Up RE: 1:1 Briefing Ann

Hello Kristin:

I am preparing the response to KEI for Dana Farber. When is it needed?

b4

Michelle sent to

b4

b4

I am pretty sure it is but need to confirm.

Ann

---

**From:** Ta, Kristin (NIH/OD) [E] <[kristin.ta@nih.gov](mailto:kristin.ta@nih.gov)>

**Sent:** Thursday, October 24, 2019 1:09 PM

**To:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>

**Subject:** Follow- Up RE: 1:1 Briefing Ann

Hi Ann,

I am pulling together Michelle's materials for her next one on one with Jodi, and she had asked me to include the responses to KEI for Jodi and Mike to clear. Following up to see when you will be able to send them to Michelle for her review.

Thanks,

Kristin

---

**From:** Bulls, Michelle G. (NIH/OD) [E] <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

**Sent:** Monday, October 21, 2019 3:40 PM

**To:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>; Bulls, Michelle G. (NIH/OD) [E] <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

**Cc:** Ta, Kristin (NIH/OD) [E] <[kristin.ta@nih.gov](mailto:kristin.ta@nih.gov)>; Bulls, Michelle G. (NIH/OD) [E] <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

**Subject:** 1:1 Briefing Ann

**Importance:** High

1:1 w/Ann

b4

App-Xtender:

Discuss w/John S  
follow up.

b5

Ann needs docs from it....need to

iEdison:

**b5**

March-In:

**b5**

Action item:

**b5**

DRAFT Response to KEI's 3/21/18 request to Take Title to Certain Patents owned by the Dana-Farber Cancer Institute.

KEI's 3/21/2018 Request:

"The failure to make a timely disclosure of the federal funding should be seen as an attempt to evade these responsibilities and as a denial of the government's rights in the invention."

"KEI recommends that the federal government take title to the invention, since the lesser remedy of requiring late disclosure has not, in the past, provided an adequate incentive for patent holders to comply with the disclosure obligations."

**b5**

DRAFT

**b5**

Sincerely,

Cc: James Love, KEI

REL0000025061.0004.0001



## SUMMARY OF NIH REVIEW OF RYDAPT

**b4,b5**



**b4,b5**

AH 12/13/2018 rev. 09/25/2019

**b4,b5**

July 24, 2019 and August 27, 2019

---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 11/14/2019 3:34:38 PM  
**To:** Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]  
**Subject:** FW: Rydapt - failure to disclose federal funding  
**Attachments:** ANNEX-KEI-Briefing-Note-2018-1.pdf; ANNEX-griffin-CA36167-NIH-REPORTER.pdf; ANNEX-james-griffin-NIH-RePORTer-20March2018.pdf; Rydapt-james-griffin-dana-farber-novartis-21Mar2018.pdf; AnnHammersla-Rydapt-20March2018.pdf; RE: Draft Responses to KEI - Rydapt

Michelle:

I have attached the Rydapt request that we received from KEI that you requested. KEI's request was in several parts. (See your attached email.) On page 11 of the above attachment entitled "Rydapt-james-griffin-dana-Farber-novartis-21Mar2018.pdf", the specific KEI request can be found. I have also copied it below. Let me know if you need any additional information. Ann

The failure to make a timely disclosure of the federal funding should be seen as an attempt to evade these responsibilities and as a denial of the government's rights in the invention. KEI recommends that the federal government take title to the invention, since the lesser remedy of requiring late disclosure has not, in the past, provided an adequate incentive for patent holders to comply with the disclosure obligations.

**From:** Andrew Goldman <andrew.goldman@keionline.org>  
**Sent:** Wednesday, March 21, 2018 8:09 AM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Cc:** Jamie Love <james.love@keionline.org>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>  
**Subject:** Re: Rydapt - failure to disclose federal funding

Dear Ann:

Thank you for your reply. Attached please find five pdf documents concerning the Rydapt issue I mentioned yesterday:

- (1) a brief cover letter regarding the Rydapt issue;
- (2) the memorandum on the failure to disclose (Rydapt-james-griffin-dana-farber-novartis-21Mar2018);
- (3) ANNEX: James Griffin's 71 NIH Funded Projects (ANNEX-james-griffin-NIH-RePORTer-20March2018);
- (4) ANNEX: Griffin's CA36167 Grants, from NIH REPORTER (ANNEX-griffin-CA36167-NIH-REPORTER)
- (5) ANNEX: KEI-Briefing-Note-2018-1

Thank you for your attention to this matter.

Sincerely,  
Andy

—  
Andrew S. Goldman  
Counsel, Policy and Legal Affairs  
Knowledge Ecology International

REL0000025061.0005

[andrew.goldman@keionline.org](mailto:andrew.goldman@keionline.org) // [www.twitter.com/ASG\\_KEI](https://www.twitter.com/ASG_KEI)  
tel.: +1.202.332.2670  
[www.keionline.org](http://www.keionline.org)

On Tue, Mar 20, 2018 at 3:27 PM, Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)> wrote:

Dear Andrew:

Thank you for your courtesy notice that KEI is submitting a new request asking the NIH to take ownership actions for Rydapt.

NIH will review the Rydapt request and NIH's funding, if any, and is now reviewing the earlier requests you have submitted and will you and KEI know the results of NIH's internal research.

Ann

--

Ann M. Hammersla, J.D.

Director

Division of Extramural Inventions and Technology Resources

Office of Policy for Extramural Research Administration

Rockledge 1, Suite 310

6705 Rockledge Drive

Bethesda, Maryland 20892-7974

PHONE: 301-435-0745

**From:** Andrew Goldman <[andrew.goldman@keionline.org](mailto:andrew.goldman@keionline.org)>  
**Sent:** Tuesday, March 20, 2018 1:22 PM  
**To:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Cc:** Jamie Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Rydapt - failure to disclose federal funding

REL0000025061.0005

Dear Dir. Hammersla:

I wanted to provide you a courtesy notice that we are finalizing a document similar to the two we have sent in recent days, this time requesting that NIH conduct an investigation into the failure to disclose federal funding leading to the expensive medicine Rydapt (INN midostaurin). The document requests that NIH remedy that failure by taking title to the patents at issue. The memorandum and appendices will detail the grants issued to inventor James Griffin, and their relationship to the patents.

Kind regards,

Andrew S. Goldman

Counsel, Policy and Legal Affairs

Knowledge Ecology International

[andrew.goldman@keionline.org](mailto:andrew.goldman@keionline.org) // [www.twitter.com/ASG\\_KEI](https://www.twitter.com/ASG_KEI)

tel.: [+1.202.332.2670](tel:+12023322670)

[www.keionline.org](http://www.keionline.org)

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**From:** Bulls, Michelle G. (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B366F1A4382D44C1BDE626E7730C3DD4-BULLSMG]  
**Sent:** 11/1/2019 2:55:51 PM  
**To:** Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** RE: Draft Responses to KEI - Rydapt

Can you resend me KEIs request so that I can make sure our response is clear.

**From:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Sent:** Thursday, October 31, 2019 12:31 PM  
**To:** Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>  
**Subject:** Draft Responses to KEI - Rydapt

Michelle:

Based on our discussion this morning I have attached two versions of the NIH response to KEI's request on Rydapt. The first attachment

b5

b5

The second draft

b5

Ann

Ann M. Hammersla, J.D.  
Director, Division of Extramural Inventions  
and Technology Resources  
Office of Policy for Extramural Research Administration

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**From:** Prabhu, Yogikala (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6DC0FA019B424F05B6F86D734D5B894A-PRABHUYO]  
**Sent:** 2/10/2020 9:32:20 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Tung, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=673ea50c713a457f82e4c3ecbf361d03-tungpp]  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Attachments:** KEI response letter- Teralimmune license-YP -Feb7.docx; KEI Comments re Exclusive Patent License in Regulatory T-cells for Treatment of Hemophilia A to Teralimmune, Inc. .pdf; Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

Dear Mark,

Please find attached our draft response letter to KEI for your review and comments. Also attached is a copy of comments from KEI for your reference.

Thank you very much!  
Best Regards,  
Yogi

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, February 4, 2020 3:56 PM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <yogikala.prabhu@nih.gov>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Tung, Peter (NIH/NIAID) [E] <peter.tung@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

I would suggest:

b5

b5

b5

Happy to review your

draft.

Thanks

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <yogikala.prabhu@nih.gov>  
**Sent:** Tuesday, February 4, 2020 3:18 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Tung, Peter (NIH/NIAID) [E] <peter.tung@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Dear Mark,

Thank you very much for your review and comments. However, we received a formal letter from KEI (please see attached). Kindly let us know your thoughts/suggestions.

Best Regards,  
Yogi

REL0000025062

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, February 4, 2020 1:18 PM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

Thanks for sending this. I have proposed edits attached;

b5

b5

Happy to answer questions.

Regards,

Mark

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Sent:** Monday, February 3, 2020 11:42 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dear Mark,

We have received questions from KEI regarding the Federal Register Notice 2020–00721, entitled “*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*,” published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!

Best Regards,

Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Monday, February 3, 2020 11:37 AM

**To:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>

**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>

**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

You need to forward this to Mark and copy me.

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
NII Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

---

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>

**Sent:** Monday, February 03, 2020 11:24 AM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>

**Subject:** KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

**Importance:** High

Dear Dale,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!

Best Regards,

Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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REL0000025062

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**b5**

**b5**



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

February 3, 2020

Dr. Yogikala Prabhu  
Technology Transfer and Patent Specialist  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
5601 Fishers Lane, Suite 6D, MSC9804  
Rockville, MD 20852-9804  
Via email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

**Re: "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)"**

Dear Dr. Prabhu:

Knowledge Ecology International (KEI) is writing to comment on "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)"<sup>1</sup> to TeraImmune, Inc. ("TeraImmune"), a start-up located in Maryland.

The federal government has conducted the basic and preclinical research for the invention and has granted TeraImmune over \$3 million to support its commercial development.

Yong Chan Kim, one of the co-inventors of the technology while employed with the National Institutes of Health (NIH), is TeraImmune's Chief Scientific Officer.

Due to the invention's indication in acquired Hemophilia A, a rare disorder and unmet health need,<sup>2</sup> it is likely to qualify for valuable regulatory incentives such as orphan drug market exclusivity and expedited FDA review.

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<sup>1</sup> 85 FR 3062, available at

<https://www.federalregister.gov/documents/2020/01/17/2020-00721/prospective-grant-of-exclusive-patent-license-development-of-regulatory-t-cell-therapies-for-the-treatment-of-hemophilia-a>.

<sup>2</sup> <https://rarediseases.org/rare-diseases/hemophilia-a/>;  
<https://rarediseases.org/rare-diseases/acquired-hemophilia/>.

The NIH must account for the value of the invention when negotiating this prospective license, and it must seek the advice of the United States Attorney General concerning antitrust law before executing it.

If the NIH proceeds with the license after conducting the necessary analysis and determining that it satisfies Section 209 of the Bayh-Dole Act, KEI requests that the license incorporates provisions designed to safeguard the public's investment and interest in the technology, as well as the stated policy objectives of the Public Health Service (PHS) Technology Transfer Manual.

## **Background**

### The Invention

The proposed license involves an invention titled "Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells," U.S. Patent No. 9,481,866,<sup>3</sup> and U.S. Divisional Application No. 15/284,840.<sup>4</sup>

The inventors listed in the patent are Yong Chan Kim and Ethan Shevach. Kim, who is the Chief Scientific Officer of TeraImmune, was employed with National Institute of Allergy and Infectious Diseases (NIAID) until December of 2011 - the month U.S. Provisional Patent Application 61/576,837, priority to U.S. patent 9,481,866, was filed. Co-inventor Ethan Shevach is an immunologist with NIAID.

The 9,481,866 patent is directed to "methods for producing cell populations enriched for stable, regulatory T cells (Tregs)." The 15/284,840 patent application is directed to "methods for producing cell populations enriched for stable, regulatory T cells (Tregs)" and compositions "enriched for stable, regulatory T cells." The "Potential Commercial Applications" for the invention are "autoimmune diseases, such as Graft vs. Host Disease, Organ Graft Rejection Type 1 Diabetes, Multiple Sclerosis."<sup>5</sup>

### Terms of the License

The license territory will be the United States and the field of use "will be limited to

<sup>3</sup>

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=1&f=G&f=50&co1=AND&d=PTXT&s1=9,481,866&OS=9,481,866&RS=9,481,866>

<sup>4</sup>

<http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetacgi%2FPTO%2Fsrchnum.html&r=1&f=G&f=50&s1=%2220170022478%22.PGNR.&OS=DN/20170022478&RS=DN/20170022478>

<sup>5</sup> <https://www.ott.nih.gov/technology/e-279-2011>.

'Human cell-based therapeutics for the treatment of Hemophilia A in patients that have inhibitory Factor VIII antibodies.'"<sup>6</sup>

The Federal Register notice does not state the proposed duration of the license, and the NIH did not respond to our question about the license term.

#### Prospective Licensee

TeralImmune is a limited liability company located in Maryland and incorporated in Delaware.

From what we can tell, TeralImmune was formed in order to develop regulatory T-cells as a platform technology with indications in various autoimmune disorders for a worldwide market.

In a pitch to investors accessible at YouTube.com, Kim and TeralImmune CEO Jay Park, Ph.D., discuss the company's plans for developing the invention, which they call "T-regs" or "T-reg therapy."<sup>7</sup>

Kim states that the invention will treat Hemophilia A in patients that have developed inhibitory Factor VIII antibodies, and in doing so, will fulfill an unmet health need.

Park says that the potential market for the invention is \$700 million in the U.S. and \$2 billion worldwide in five years. He states that TeralImmune "will further explore autoimmune diseases with its platform technology. The next one will be multiple sclerosis." The video states that the global market size is \$2 billion annually for Hemophilia A and \$100 billion for autoimmune disorders.

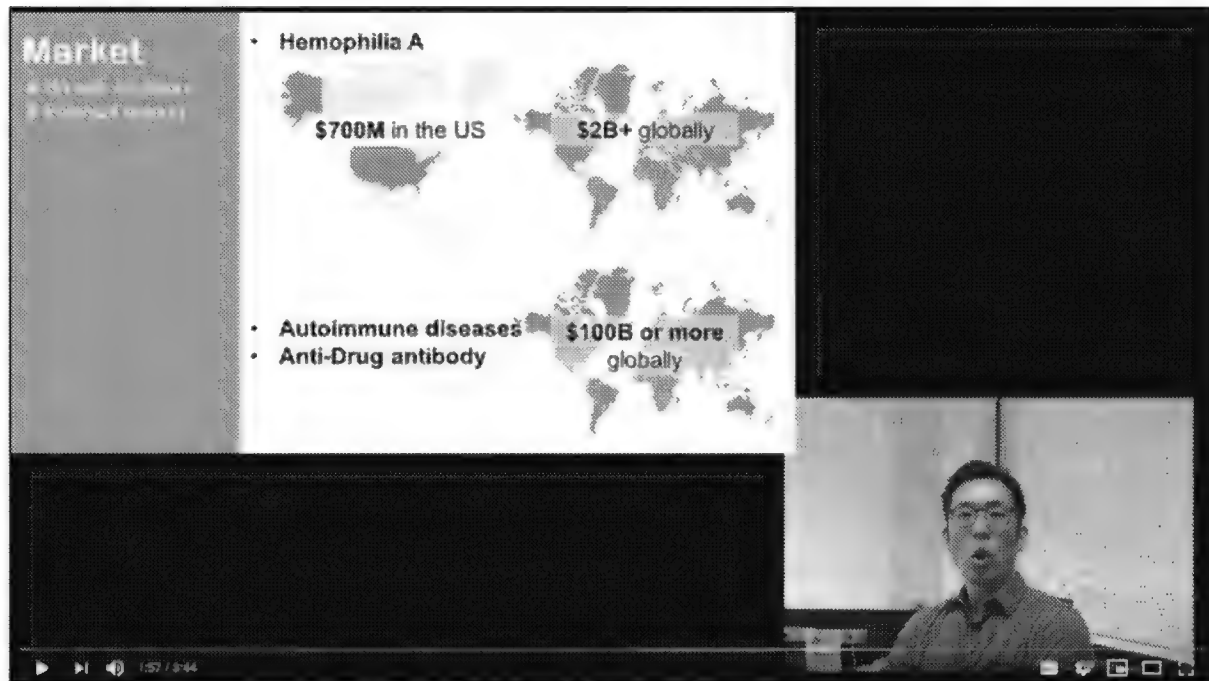
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6

<https://www.federalregister.gov/documents/2020/01/17/2020-00721/prospective-grant-of-exclusive-patent-license-development-of-regulatory-t-cell-therapies-for-the>.

<sup>7</sup> <https://www.youtube.com/watch?v=5CFK7wHRdyU>.





Treg therapy (Teraimmune, Inc.), UKC 2019 Startup Pitch in English

120 views • Jun 25, 2019

Like 2 Dislike 0 Share 0 Save 0

The video includes a side-by-side comparison of Teraimmune, Kite Pharma, Juno Therapeutics, and Cabaletta Bio. It notes that Kite and Juno were acquired for \$11.9 billion and \$9 billion (respectively) and projects that Teraimmune will be acquired for more than \$5 billion.

According to the video, Teraimmune received \$3,225,000 in public funding from the NIH to develop its Treg therapy (\$225,000 from an SBIR grant, and \$3 million from a PACT grant).

The company is seeking \$8 million from investors to conduct a Phase I clinical trial to test the invention in patients with Hemophilia A.

## Discussion

1. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license or that it has ensured that the scope of rights will not be broader than reasonably necessary to induce the investment needed to commercialize the subject technology.

The NIH may not license an invention on an exclusive basis unless, among other criteria, it finds that:



(1) “granting the license is a reasonable and necessary incentive to -- (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public;” and

(2) “the public will be served by the granting of the license ... and [] the proposed scope of exclusivity is not greater than reasonably necessary[.]”

35 U.S.C. § 209(a)(1)-(2).

Determining the incentive necessary for bringing an invention to practical application is a fact-specific inquiry: As the NIH has acknowledged, “[t]he value of patent commercialization licenses are not uniform and depend on many factors[.]” These factors include:

- The potential market size of the drug or biologic;
- “Existing incentives, such as the Orphan Drug Act, and fast track FDA review that affect how quickly the drug can be brought to market and offer financial incentives”;
- Clinical trial costs; and
- “Projected manufacturing costs upon FDA approval[.]”<sup>8</sup>

Another important factor influencing the value of a biomedical invention is its stage of research and development. As Dr. Mark Rohrbaugh<sup>9</sup> testified to Congress, “[t]he closer a technology is to the marketplace, the lower the risk and cost to the licensee, and the more valuable the technology[.]”<sup>10</sup>

Below is a discussion of how the relevant factors bear on the invention’s commercial value.

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<sup>8</sup> Aylin Sertkaya et al., U.S. Dept. of Health & Hum. Serv., *Examination of Clinical Trial Costs and Carriers for Drug Development* (2014),

<https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development>.

<sup>9</sup> Special Advisor for Technology Transfer to the NIH Deputy Director for Intramural Research.

<sup>10</sup> Mark L. Rohrbaugh, *NIH: Moving Research from the Bench to the Bedside, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health*, July 10, 2003, available at

<https://www.govinfo.gov/content/pkg/CHRG-108hhrg88429/html/CHRG-108hhrg88429.htm>.

### *Research and Development Stage & Cost of Additional R&D Required to Bring Invention to Market*

The development stage of the technology is “preclinical.” In the investment pitch video, Park states that Teralmmune hopes to raise \$8 million for a Phase I clinical trial to investigate T-regs in Hemophilia A patients. Eight million dollars is a notable contrast from the “hundreds of millions of dollars” Dr. Rohrbaugh has claimed it costs to conduct clinical trials in cell and gene therapies, as a justification for granting expansive license terms in NIH-owned inventions. It is consistent with KEI’s research of the cost of clinical trials in cell and gene therapies.

### *Government Investment in the Technology*

In addition to the intramural support for the invention’s basic and preclinical research, Teralmmune is benefitting from at least two federal grants totalling nearly \$3.25 million to support the commercial development of the technology.

The first, 1R43HL140748-01A1, is a Small Business Innovation Research (SBIR) Grant for \$224,941 awarded by the National Heart, Lung, and Blood Institute (NHLBI) to Teralmmune in 2018. The title of the grant is “Factor VIII (FVIII)-Specific Therapeutic Tregs and Related CGMP Manufacturing Process for Hemophilia A Patients with Inhibitors.”

NHLBI also awarded Teralmmune a “Production Assistance for Cellular Therapies” (PACT) grant worth \$3 million. According to the NHLBI, “Production Assistance for Cellular Therapies (PACT) is a National Heart, Lung, and Blood Institute (NHLBI) funded resource initiative, comprised of five Cell Processing Facilities and a Coordinating Center, created to provide regulatory services, assistance with cellular therapy translational research and the manufacture of cellular therapy products.”<sup>11</sup>

According to the “Results” tab for the SBIR Grant at [projectreporter.nih.gov](https://projectreporter.nih.gov), the PACT grant is covering all of Teralmmune’s costs in developing “Standard Operating Procedures (SOPs) for the manufacture and supply of Tregs to the clinical site for the initial clinical trial” as well as all cell production costs. The Results webpage states further that Teralmmune has participated in a “pre-pre-IND” (Initial Targeted Engagement for Regulatory Advice) meeting with the FDA’s Center for Biologics Evaluation and Research regarding the invention, “with supports from the PACT program and Emmes Corporation, a Clinical Research Organization.”

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<sup>11</sup> <https://www.pactgroup.net/>.

### *Regulatory Incentives*

Another factor relevant to an invention's commercial value is the availability of regulatory incentives, such as orphan drug status, that provide additional market exclusivities and expedited FDA review.<sup>12</sup>

Hemophilia A is a rare disorder,<sup>13</sup> and, according to Kim, Hemophilia A with inhibitory Factor VIII antibodies is an unmet health need. The invention is thus likely to qualify for these incentives, which include a 25 percent tax credit and seven years of Orphan Drug regulatory exclusivity.

### *Potential Revenues*

The Teralmmune investor pitch states that Hemophilia A has a market size of \$700 million in the United States.

Teralmmune considers the invention to be a profitable investment. The company expects to be worth \$200 million at the time of an IPO and more than \$5 billion when it is acquired.

### *The NIH's Analysis of the License*

KEI asked Dr. Yogikala Prabhu, the point of contact for the license, whether the NIH had conducted an economic analysis of what would be required to bring the invention to practical application. We also asked about the terms of the license and how the NIH will ensure that they satisfy the Bayh Dole Act. As of the date of these comments, he has not responded.

KEI's past correspondence with the NIH about its licensing practice indicates that the agency routinely grants exclusive, life-of-patent licenses in cell and gene therapies.

For example, a letter to KEI from Dr. Rohrbaugh dated November 26, 2019 states as follows:

- "[NIH] works in a market for these early-stage therapeutic technologies in which there is *essentially no demand for nonexclusive licenses*."
- "[C]ompanies and investors have choices as to which early stage technologies to develop and, in taking on this risk and committing to commercialization, *require an exclusive license for the full patent term*."<sup>14</sup>

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<sup>12</sup> <https://www.priorityreviewvoucher.org/>.

<sup>13</sup> <https://rarediseases.org/rare-diseases/hemophilia-a/>.

<sup>14</sup> *Id.*

If, in fact, the NIH has not assessed the commercial potential of the covered invention on an individualized basis, it has not satisfied Section 209(a)(1)-(2) of the Bayh-Dole Act for the instant license.

2. Under 40 U.S.C. § 559, the NIH is required to obtain the antitrust advice of the United States Attorney General before executing the license.

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license would not be anticompetitive.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property,” with certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term “property” in Section 559 includes intellectual property rights such as patents.

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

“The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.”

The NIH’s interpretation of 40 U.S.C. § 559 is incorrect.



The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If the NIH has not consulted with the Attorney General regarding the license, it has not complied with 40 U.S.C. § 559.

3. In the event that the NIH decides to grant the license, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles in the PHS Technology Transfer Manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public’s interest in the technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddi case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than

reasonably necessary to provide the incentive for bringing the invention to practical application.”

3. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

### **Concluding comments**

We support the NIH’s efforts to license the subject invention to a commercial partner who appears to be qualified to bring it to practical application.

It is our understanding that licensing a patent to a company employing the inventor does have the advantage that the inventor may bring unique insights into the technology, and a passion to see the technology reach the market. That said, it does raise some issues regarding the self dealing at the NIH, with government funded inventions being licensed to former employees. This is particularly relevant given the general lack of interest by the NIH in negotiating licensing terms that protect the public from excessive monopoly power over this taxpayer funded invention. In this regard, KEI notes that the company claims that it requires just \$8 million for the proposed clinical trial, and that the company sees the market for the licensed technology to reach \$2 billion per year, for the Hemophilia A indication (of which 35 percent will come from U.S. patients). Further, the company business plan is to sell out to another company for more than \$5 billion. This suggests that the proposed license is a better deal for Teralmmune than it is for the public that has financed the R&D so far. Also, Teralmmune is likely to charge extremely high prices if the license is granted and the technology reaches the U.S. market.

The terms of the license must satisfy the Bayh-Dole Act and federal regulations, and before the NIH executes the license, it must consult the United States Attorney General. Finally, KEI requests that the license incorporates the provisions listed above, which are designed to promote the public interest in the invention and implement the policy objectives of the PHS Technology Transfer manual.

Sincerely,

Knowledge Ecology International

---

**From:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**Sent:** 1/28/2020 3:21:41 PM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc0fa019b424f05b6f86d734d5b894a-prabhuyo]  
**Subject:** Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

Dear Dr. Prabhu:

At your earliest convenience, please answer the questions below, which concern the "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)."

1. At what stage of research and development is the technology?
2. Has the invention been investigated in any clinical trials? If so, what are their NCT numbers?
3. How much funding has the government contributed to the development of the technology? What NIH Grant Nos. are associated with it?
4. What is the proposed duration of the license?
5. What analysis was performed in determining that an exclusive license was a necessary incentive and otherwise satisfies 35 U.S.C. 209?
6. How will the NIH ensure that the scope of the license is not broader than reasonably necessary?
7. Please provide a list of firms that applied for this license. Please note that KEI is only seeking the name of any license applicants, and not any confidential material within the license applications.
8. How was Teralmmune selected as the prospective licensee over any other bidders? Did the NIH consider the company's relationship with Yong Chan Kim, the former NIH scientist who invented the technology?

Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 10/3/2019 2:58:59 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, October 03, 2019 10:56 AM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

No. b5

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Thursday, October 3, 2019 10:54 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Are you saying that b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, October 03, 2019 10:48 AM  
**To:** James Love <james.love@keionline.org>  
**Cc:** kathryn ardizzone <kathryn.ardizzone@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Jamie:

The first one is old language we have used for decades referencing the FOIA office's ability to make documents available for "public inspection". Public inspection means literally that, a place where one can physically inspect documents. It does not necessarily mean that documents are confidential because they are not available for public inspection. Comments and objections, other than those in the form of a completed license application will not be treated confidentially but they are not placed somewhere for public inspection.

Regards,  
Mark

REL0000025066

**From:** James Love <james.love@keionline.org>

**Sent:** Thursday, October 3, 2019 9:35 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>

**Cc:** kathryn ardizzone <kathryn.ardizzone@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>

**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

For a recent license, noticed today, October 3, 2019,

<https://www.federalregister.gov/documents/2019/10/03/2019-21520/prospective-grant-of-an-exclusive-patent-license-compositions-devices-and-processes-for-production>

The rule was that comments by third parties "may be made publicly available."

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

However, for your Sept 27, 2019, notice:

<https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>

You take the opposite position.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

How can you possibility claim objections to this license are confidential, while objections to others, some more recent even, are not confidential?

Is this an abuse of your discretion, or a misreading of the law by someone?

Jamie

On Wed, Oct 2, 2019 at 11:02 PM Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov> wrote:

Dear Kathryn,

Thanks for your inquiry. Please see my answers to your questions below. I hope I answered them in full.

Best regards,

Uri

Uri Reichman, Ph.D, MBA

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development (OTTAD)

NHLBI/NIH

Bethesda, MD

301-435-4616 (o)

443-938-0972 (m)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Wednesday, October 2, 2019 10:25 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>

**Subject:** Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

Early stage.

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

No!

3. How much has the NIH spent to support the development of the invention?

I do not have this information.

4. Is the period of exclusivity to be life of patent or less than life of patent?

It will be negotiated. Typically exclusive licenses are for the term of the patent.

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

It is determined on a case by case basis.

6. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?
7. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

The license application is legally protected as confidential to the company.

8. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary? Confidential information from the license application is used to draft an appropriate field of use.
9. What criteria was used to select Generation Bio selected as licensee? 37 CFR 404 provides the criteria used by the agency to evaluate patent license application.
10. When did Generation Bio submit its license application? August 2019
11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not? No!
12. What diseases fall within the field of use for the exclusive license to Generation Bio?

This is the broadest possible scope. It will be negotiated with the company if the NIH moves forward with the license.

13. Please provide a list of other firms that expressed an interest in this license.

Applications are confidential.

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

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Washington, DC 20009

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**From:** Feliccia, Vincent (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F3A54860CB941C1ABE1DF786E478E00-VFELICCIA]  
**Sent:** 8/17/2020 5:40:31 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4ec05a179f04067b61f20605e911e7c-petrika]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Salata, Carol (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98ca6a1f9fc4cfdbbf4036ca8cbace4-csalata]  
**Subject:** RE: Question about 83 FR 16376

Hello Everyone,

My two cents,

b5

b5

Regards,

Vince

\*\*\*\*\*

**Vincent L. Feliccia, Ph.D., J.D.**

Branch Chief

Vaccine Design, Allergic and Infectious Diseases Branch (VDAID)

Technology Transfer and Intellectual Property Office (TTIPO)

National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

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[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)

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**From:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>

**Sent:** Friday, August 14, 2020 2:08 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>

REL0000025067

**Cc:** Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>  
**Subject:** FW: Question about 83 FR 16376

FYI response below – thanks for everyone’s help with this matter!

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 2:05 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you, that makes sense. Unfortunately, in my experience reviewing proposed exclusive licenses, this is often not the case. I have seen many exclusive licenses to platform technologies (though mostly the inventions were owned by NCI). I do appreciate your answers to my questions, even though you feel you are not able to disclose the identity of other license applications when under federal law, it is only the licensee's commercialization plan that is confidential under the license application.

On Fri, Aug 14, 2020 at 1:48 PM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

This technology has the potential to be useful for many coronavirus vaccines. As such, we consider it a platform technology. A platform technology is normally licensed non-exclusively or on an exclusive basis with multiple narrow fields of use.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 10:58 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Can you tell me why NIAID decided to go non-exclusive on this invention?

On Fri, Aug 14, 2020 at 10:55 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

NIAID’s license negotiations are considered proprietary and I can’t discuss the identity of parties or subjects of discussion.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 10:47 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Re: Question about 83 FR 16376

Thank you. With Moderna?

On Fri, Aug 14, 2020 at 10:42 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

Yes, these are nonexclusive license agreements and there are others in negotiation.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>

**Sent:** Friday, August 14, 2020 10:40 AM

**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you.

So I guess it's a non-exclusive license? Will there be future licenses?

Kathryn

On Fri, Aug 14, 2020 at 10:37 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

Hi Kathryn,

The following organizations have licensed the technology discussed in the subject Federal Register notice (HHS Ref. No. E-234-2016):

Medigen Vaccine Biologics Corp.

Noachis Terra, Inc.



OncoSec Medical Incorporated

BioNTech AG

N4 Pharm UK Limited

Dynavax Technologies

RNAceuticals, Inc.

Sanofi Pasteur

GlaxoSmithKline Biologicals SA

Adimmune Corporation

Vaxess Technologies

Meso Scale Diagnostics, LLC

The Binding Site Group Ltd.

Best,

Amy

**From:** Kathryn Ardizzone <[kathrynardizzonekei@gmail.com](mailto:kathrynardizzonekei@gmail.com)>

**Sent:** Thursday, August 13, 2020 4:19 PM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you for your response. Of course you understand that the FOIA requires agencies to produce records but does not PRECLUDE agency officials from answering members of the public's questions. I didn't ask for records, just a simple question. So a FOIA request would not be the proper route. In addition, I'm still awaiting a FOIA request from March that was granted expedited processing— no word on a response almost 6 months later. But again, I don't have to go through the FOIA. You could just answer my question. It's a very simple matter that the public has the right to know the basic fact over whether a license to a publicly-owned technology was executed.

What is keeping you from answering my question? Your confidentiality agreement with Moderna?

REL0000025067

Best,

Kathryn

On Thu, Aug 13, 2020 at 4:13 PM Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)> wrote:

Dear Kathryn,

Such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests:

[www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests](http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests)

Best,

Amy

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Tuesday, August 11, 2020 8:58 PM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Question about 83 FR 16376

Dear Ms. Petrik,

Has the NIH ever executed a license over the technology listed as available for licensing here: <https://www.federalregister.gov/documents/2018/04/16/2018-07822/government-owned-inventions-availability-for-licensing>? If so, who is the licensee? When was the license executed?

Thank you,

Kathryn Ardizzone, Esq.

Counsel

REL0000025067

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

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Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

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1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AaffA5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/3/2019 1:54:13 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Hi Mark and Dale,

Does this mean that

b5

b5

**From:** James Love <james.love@keionline.org>  
**Sent:** Thursday, October 3, 2019 9:35 AM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Cc:** kathryn ardizzone <kathryn.ardizzone@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

For a recent license, noticed today, October 3, 2019,  
<https://www.federalregister.gov/documents/2019/10/03/2019-21520/prospective-grant-of-an-exclusive-patent-license-compositions-devices-and-processes-for-production>

The rule was that comments by third parties "may be made publicly available."

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

However, for your Sept 27, 2019, notice:

<https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>

You take the opposite position.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

How can you possibly claim objections to this license are confidential, while objections to others, some more recent even, are not confidential?

Is this an abuse of your discretion, or a misreading of the law by someone?

Jamie

On Wed, Oct 2, 2019 at 11:02 PM Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)> wrote:

Dear Kathryn,

Thanks for your inquiry. Please see my answers to your questions below. I hope I answered them in full.

Best regards,

Uri

Uri Reichman, Ph.D, MBA

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development (OTTAD)

NHLBI/NIH

Bethesda, MD

301-435-4616 (o)

443-938-0972 (m)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Wednesday, October 2, 2019 10:25 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>

REL0000025068

**Subject:** Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

Early stage.

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

No!

3. How much has the NIH spent to support the development of the invention?

I do not have this information.

4. Is the period of exclusivity to be life of patent or less than life of patent?

It will be negotiated. Typically exclusive licenses are for the term of the patent.

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

It is determined on a case by case basis.

6. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?
7. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

The license application is legally protected as confidential to the company.

8. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary? Confidential information from the license application is used to draft an appropriate field of use.
9. What criteria was used to select Generation Bio selected as licensee? 37 CFR 404 provides the criteria used by the agency to evaluate patent license application.
10. When did Generation Bio submit its license application? August 2019
11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not? No!
12. What diseases fall within the field of use for the exclusive license to Generation Bio?



This is the broadest possible scope. It will be negotiated with the company if the NIH moves forward with the license.

13. Please provide a list of other firms that expressed an interest in this license.

Applications are confidential.

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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James Love. Knowledge Ecology International

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U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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**From:** NIH FOIA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E734B867D58F45E792D9FA7096AA146D-NIHFOIA]  
**Sent:** 8/14/2020 8:49:35 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** NIH FOIA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e734b867d58f45e792d9fa7096aa146d-nihfoia]  
**Subject:** RE: NIH FOIA Request for Input - 54587 CassedyGor

Thank you Mark,

I'm not sure, but I will check with Gorka and let you know.

- Roger

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, August 14, 2020 4:48 PM  
**To:** Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>  
**Cc:** NIH FOIA <nihfoia@od.nih.gov>  
**Subject:** RE: NIH FOIA Request for Input - 54587 CassedyGor

Roger:

Thanks. I thought it would be to the present as of the date of the request (June 18), otherwise, the date keeps getting later. Also, Gorka told me at the beginning of July, that he would have CIT pull all my emails with these key words. Was that done?

Regards,  
Mark

---

**From:** Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>  
**Sent:** Friday, August 14, 2020 4:41 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** NIH FOIA <nihfoia@od.nih.gov>  
**Subject:** NIH FOIA Request for Input - 54587 Cassedy

Good Afternoon,

Please see the attached request for input regarding a copy of all correspondence to and from Dr. Mark L. Rohrbaugh, Special Advisor for Technology Transfer, that mention and/or concern the following:

- "Knowledge Ecology International", or "KEI";
- James Love;
- Andrew Goldman; or
- Kathryn Ardizzone.

The period of this request is from January 1, 2015 to the present.

Please let us know if you have any questions.

**Roger Bordine**

REL0000025069

Program Support  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633  
Fax: 301-402-4541  
[Roger.bordine@nih.gov](mailto:Roger.bordine@nih.gov)



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**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 10/3/2019 2:31:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Yes but I have a 10:30 call. Will try to catch you after.

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, October 03, 2019 10:27 AM  
**To:** Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Can we talk about this. I am at 301 827 9689

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Thursday, October 3, 2019 10:17 AM  
**To:** James Love <james.love@keionline.org>  
**Cc:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dr. Reichman,

In addition to Jamie's comments, I would add that under a plain reading of the relevant federal regulations, only one component of a license application must be treated as confidential - the applicant's development plan. Other aspects of the plan are not confidential.

**37 CFR § 404.14, Confidentiality of information**, clearly states that "any **plan** submitted pursuant to **§ 404.8(h)** and any report required by **§ 404.5(b)(6)** shall be treated as commercial or financial information obtained from a person and privileged and confidential[.]"

**§ 404.8(h), Application for a license**, lists 11 different components of a license application. Only one of those components - 404.8(h)(a)(8) - refers to a **plan**. Thus, under any straightforward reading of 37 CFR § 404.14 and § 404.8(h), the only confidential aspect of a license application is the plan described at 404.8(h)(a)(8). If the drafters of the regulation intended to include *all components* of a license application, they could have easily written 37 CFR § 404.14 to state that "any **license application** submitted pursuant to § 404.8(h) shall be treated as confidential." They did not. At the risk of sounding repetitive, § 404.14 was explicitly limited to plans. So, for example, the identity of an applicant 404.8(h)(a)(3) is not made confidential under 37 CFR § 404.14.

NIH has an obligation to abide by the law as it is written. Please explain how, in the NIH's view, 37 CFR § 404.14 and § 404.8(h) could be interpreted other than how I have just laid out.

Sincerely,  
Kathryn Ardizzone

On Thu, Oct 3, 2019 at 9:35 AM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:

For a recent license, noticed today, October 3, 2019,  
<https://www.federalregister.gov/documents/2019/10/03/2019-21520/prospective-grant-of-an-exclusive-patent-license-compositions-devices-and-processes-for-production>

The rule was that comments by third parties "may be made publicly available."

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

However, for your Sept 27, 2019, notice:

<https://www.federalregister.gov/documents/2019/09/27/2019-20992/prospective-grant-of-exclusive-patent-license-capsid-free-aav-vectors-compositions-and-methods-for>

You take the opposite position.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

How can you possibly claim objections to this license are confidential, while objections to others, some more recent even, are not confidential?

Is this an abuse of your discretion, or a misreading of the law by someone?

Jamie

On Wed, Oct 2, 2019 at 11:02 PM Reichman, Uri (NIH/NHLBI) [E] <[uri.reichman@nih.gov](mailto:uri.reichman@nih.gov)> wrote:

Dear Kathryn,

Thanks for your inquiry. Please see my answers to your questions below. I hope I answered them in full.

Best regards,

Uri

Uri Reichman, Ph.D, MBA

REL0000025070

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development (OTTAD)

NHLBI/NIH

Bethesda, MD

301-435-4616 (o)

443-938-0972 (m)

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Wednesday, October 2, 2019 10:25 AM

**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>

**Cc:** James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>

**Subject:** Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

Early stage.

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

No!

3. How much has the NIH spent to support the development of the invention?

I do not have this information.

4. Is the period of exclusivity to be life of patent or less than life of patent?

It will be negotiated. Typically exclusive licenses are for the term of the patent.



5.If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

It is determined on a case by case basis.

6.Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

7.For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

The license application is legally protected as confidential to the company.

8.For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary? Confidential information from the license application is used to draft an appropriate field of use.

9.What criteria was used to select Generation Bio selected as licensee? 37 CFR 404 provides the criteria used by the agency to evaluate patent license application.

10. When did Generation Bio submit its license application? August 2019

11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not? No!

12. What diseases fall within the field of use for the exclusive license to Generation Bio?

This is the broadest possible scope. It will be negotiated with the company if the NIH moves forward with the license.

13. Please provide a list of other firms that expressed an interest in this license.

Applications are confidential.

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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James Love. Knowledge Ecology International  
U.S. Mobile +1.202.361.3040  
U.S. office phone +1.202.332.2670  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



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**From:** Bordine, Roger (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A44282B444584690BBBE471966F54F1F-BORDINERW]  
**Sent:** 8/14/2020 8:41:27 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** NIH FOIA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e734b867d58f45e792d9fa7096aa146d-nihfoia]  
**Subject:** NIH FOIA Request for Input - 54587 Cassedy  
**Attachments:** NIH FOIA Request from KEI - 54587 Cassedy.pdf

Good Afternoon,

Please see the attached request for input regarding a copy of all correspondence to and from Dr. Mark L. Rohrbaugh, Special Advisor for Technology Transfer, that mention and/or concern the following:

- “Knowledge Ecology International”, or “KEI”;
- James Love;
- Andrew Goldman; or
- Kathryn Ardizzone.

The period of this request is from January 1, 2015 to the present.

Please let us know if you have any questions.

**Roger Bordine**

Program Support  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633  
Fax: 301-402-4541  
[Roger.bordine@nih.gov](mailto:Roger.bordine@nih.gov)



Knowledge Ecology International  
1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

June 18, 2020

FOIA Information Office  
Office of Technology Transfer  
National Institutes of Health  
NIH Building 31, Room 5B35  
31 Center Drive, MSC 2107  
Bethesda, MD 20892-2107  
VIA: NIH FOIA Portal

**Re: Freedom of Information Act Request Regarding Correspondence of Mark Rohrbaugh**

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552), Knowledge Ecology International (KEI) requests electronic copies of all correspondence to and from Dr. Mark L. Rohrbaugh, Special Advisor for Technology Transfer, that mention and/or concern the following:

- "Knowledge Ecology International", or "KEI";
- James Love;
- Andrew Goldman; or
- Kathryn Ardizzone.

The period of this request is from January 1, 2015 to the present.

**Request for Full Waiver of Fees**

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A), which requires a responding agency to waive FOIA fees when disclosure "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government," and "is not primarily in the commercial interest of the requester."

The subject of this request concerns the operations of the federal government because it pertains to a federal agency's role in sponsoring or conducting biomedical research and development, how it licenses technologies it has developed, how government employees interpret the related policies and practices, and how government employees approach engagement with the public concerning government licensing practices.

The disclosures will likely contribute to public understanding of the role that the federal government plays in the development of critical medical technologies. The records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain about how the NIH manages public comments regarding march-in requests and its licensing activities under 35 U.S.C. 207 and 209, responses to inquiries, and overall how the NIH interprets its obligation to engage with public regarding the licensing of taxpayer-funded NIH inventions to pharmaceutical companies.

KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *the Financial Times* and in several academic and policy journals.

The stories listed in Annex 1 demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. See *Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

### **Additional Comments**

Please provide the documents requested in electronic format.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

We look forward to your determination regarding our request for expedited processing within 10 calendar days of receiving this request, as required by 5 U.S.C. § 552(a)(6)(E)(ii).

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org).

Thank you in advance for your assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Claire P. Cassidy". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Claire Cassidy  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
[claire.cassidy@keionline.org](mailto:claire.cassidy@keionline.org)

## **ANNEX 1**

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested

records to the public. KEI operates websites including keionline.org and drugdatabase.info that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as ip-health, which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at keionline.org.

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests in the open source database drugdatabase.info:

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/nih-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "[U.S. nixed India's plea on reforms in medicine](#)," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. [Front page](#).

- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," *Inside Views, IP-Watch.Org*.

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 10/2/2019 5:23:54 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Thanks

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, October 02, 2019 1:03 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Re: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Yellow when I wanted to propose b5 This was for Uri to use b5 for answers to questions KEI just submitted.

Sent from my iPhone

On Oct 2, 2019, at 12:32 PM, Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov> wrote:

Which ones are your answers?

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, October 02, 2019 12:08 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

See my comments below as well. Dale OK?

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Wednesday, October 2, 2019 11:55 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Reichman, Uri (NIH/NHLBI) [E]

REL0000025073



<uri.reichman@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>

Cc: Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>

**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

**Importance:** High

Dear All—see below, we collectively responded.

---

Dear Dr. Reichman:

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

b5

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

b5

3. How much has the NIH spent to support the development of the invention?

b5

4. Is the period of exclusivity to be life of patent or less than life of patent?

b5

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

b5

6. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

b5

7. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

b5

8. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary?

b5



**b5**

9. What criteria was used to select Generation Bio selected as licensee?

**b5**

10. When did Generation Bio submit its license application?

**b5**

11. Does the NIH see any potential issue in licensing an invention discovered by then-NIH-employee Robert Kotin to a company which Kotin co-founded? Why or why not?

**b5**

12. What diseases fall within the field of use for the exclusive license to Generation Bio?

**b5**

13. Please provide a list of other firms that expressed an interest in this license.

**b5**

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AFFA5D8E64E8C9783C67B500D8DB8-REICHMAU]  
**Sent:** 10/2/2019 6:24:17 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Mark and Dale,

Should we [REDACTED] b5  
[REDACTED] b5

Thanks,

Uri

**From:** Reichman, Uri (NIH/NHLBI) [E]  
**Sent:** Wednesday, October 2, 2019 1:09 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Cc:** Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery  
**Importance:** High

Hey Mark and Dale,

Misha [REDACTED] b5 Please review it again [REDACTED] b5  
[REDACTED] b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Wednesday, October 2, 2019 12:45 PM  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** RE: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery  
**Importance:** High

**From:** Shmilovich, Michael (NIH/NHLBI) [E]  
**Sent:** Wednesday, October 02, 2019 12:22  
**To:** Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>  
**Subject:** FW: Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

REL0000025074

KEI is investigating the NIH exclusive patent license, "Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery," referenced at 84 FR 51171. At your earliest convenience, please answer the following questions regarding the proposed license:

1. At what stage of research and development is the subject invention?

b5

2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?

b5

3. How much has the NIH spent to support the development of the invention?

b5

4. Is the period of exclusivity to be life of patent or less than life of patent?

b5

5. If the period of exclusivity is life of patent, why wouldn't a shorter period of time suffice?

b5

6. For the first license, on what basis did the NIH conclude that an *exclusive* (as opposed to non-exclusive or partially exclusive) license to Generation Bio was a necessary incentive under 35 U.S.C. § 209(a)(1)?

b5

7. For both licenses, how has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary?

b5

8. What criteria was used to select Generation Bio selected as licensee?

b5

9. When did Generation Bio submit its license application?

b5

10. What diseases fall within the field of use for the exclusive license to Generation Bio?

b5

11. Please provide a list of other firms that expressed an interest in this license.

b5

Thank you in advance for your answers to these questions. My colleague, Luis Gil Abinader, may follow up with additional questions.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009

REL0000025074

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Knezevic, Vlado (NIH/NIDDK) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CD7FD096830401C88A2C03EC1916B3C-KNEZEVICV2]  
**Sent:** 4/28/2020 9:45:41 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Niebylski, Charles (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3248b0e1497e439b94ce47c2f52b0268-niebylskicd]  
**Subject:** Re: Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Understood.

b5

*Vlado*

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation  
Technology Advancement Office (TAO)  
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)  
National Institutes of Health  
Department of Health & Human Services  
Building 12A, Room 3011  
Bethesda, MD 20817-5632  
Office phone: 301-435-5560  
Mobile: b6  
Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Date:** Tuesday, April 28, 2020 at 5:42:20 PM  
**To:** "Knezevic, Vlado (NIH/NIDDK) [E]" <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>  
**Cc:** "Niebylski, Charles (NIH/NIDDK) [E]" <[charles.niebylski@nih.gov](mailto:charles.niebylski@nih.gov)>  
**Subject:** RE: Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Second one this week. We need to respond

b5

b5

Please send me a draft to review.

**From:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>  
**Sent:** Tuesday, April 28, 2020 5:22 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>; Niebylski, Charles (NIH/NIDDK) [E] <[charles.niebylski@nih.gov](mailto:charles.niebylski@nih.gov)>  
**Subject:** FW: Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Hello Mark – I assume this is not the first time you are seeing these.

It is my assumption that

b5

Kindly confirm.

*Vlado*

---

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation

Technology Advancement Office (TAO)  
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)  
National Institutes of Health  
Department of Health & Human Services  
Building 12A, Room 3011  
Bethesda, MD 20817-5632  
Office phone: 301-435-5560  
Mobile: b6  
Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

[www.niddk.nih.gov](http://www.niddk.nih.gov)



**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Tuesday, April 28, 2020 5:12 PM

**To:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Dear Dr. Knezevic:

Attached, please find the comments of Knowledge Ecology International and James Love regarding the "Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity" to Kriya Therapeutics, Inc."

Sincerely,  
Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

REL0000025077



---

**From:** Michael Carroll and Christine Haight Farley [pijip@wcl.american.edu]  
**Sent:** 11/14/2019 9:32:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** PIJIP Fall 2019 Update



PIJIP Update - Fall 2019

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## Events

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### Professor Ruth Okediji Delivers 8th Annual Peter A. Jaszi Distinguished Lecture on Intellectual Property

Professor Ruth Okediji delivered the 8th Annual Peter A. Jaszi Distinguished Lecture on Intellectual Property. Her lecture, titled "The Unfinished Business of Copyright Limitations and Exceptions," called for a new paradigm of thinking about the relationship between copyright and the public interest. "The excesses of the copyright system cannot be remedied by limitations and exceptions alone." [A video of her talk is available here.](#)

---

### Fall 2019 Events

Sep 3: Moving Towards a New Copyright Bargain - Lecture by Rebecca Giblin of the Author's Interest Project

Sep 5: Annual Student & Alumni Reception at Microsoft

Sep 13: Trademark &



## IP at the Supreme Court Series

Now in its 8th year, our IP at the Supreme Court series brings counsel of record and counsel for selected amici in IP (and related) cases heard by the Supreme Court together on the afternoon after the oral argument to discuss the case. Webcasts of the 43 IP at the Supreme Court events we've hosted since 2012 are available online. In December 2019, we will host events on *Georgia v. Public.Resource.Org* and *Thryv, Inc. v. Click to Call Technologies*, and in Spring 2020 we will host events on upcoming cases, including *Romag Fastners v. Fossiland*, *Lucky Brands v. Marcel Fashion*, and *USPTO v. Booking.com*.

Patent Works in  
Progress Colloquia

Sep 17: The Code:  
*Silicon Valley and the  
Remaking of America* -  
Book Talk with Author  
Margaret O'Mara

Oct 7: IP at the  
Supreme Court Series:  
*Peter v. NantKwest*

Oct 10: Prof. Ruth L.  
Okediji Delivers the 8th  
Annual Peter A. Jaszi  
Distinguished Lecture  
on Intellectual Property

Nov 1: American  
University Law Review  
Federal Circuit  
Symposium

Nov 5: IP at the  
Supreme Court Series:  
*Allen v. Cooper*

Dec. 2: IP at the  
Supreme Court Series:  
*Georgia v. Public*  
*Resources.Org*

Dec 3: IP at the  
Supreme Court Series:  
*Thryv, Inc. v. Click to*  
*Call Technologies*

## Spring 2019 Events

Jan 8: IP at the  
Supreme Court Series  
- *Fourth Estate Public*  
*Benefit Corp. v. Wall-*  
*Street.com*

Jan 14: IP at the  
Supreme Court Series  
- *Rimini Street Inc. v.*  
*Oracle USA Inc.*

Jan 17: An Expansion  
of the Commons:  
Copyright, Creative  
Commons and the  
Public Domain

Jan 29: Book Talk with  
Author Kevin Werbach  
- *The Blockchain and*  
*the New Architecture of*  
*Trust*

Feb 19: IP at the  
Supreme Court Series:  
*Return Mail Inc. v.*  
*United States Postal*  
*Service*

Feb 20: FUCT by the  
USPTO: Lunch Talk  
and Informal Moot with  
John Sommer, Counsel  
for Appellee in *Iancu v.*  
*Brunetti*

Feb 20: IP at the  
Supreme Court Series:  
*Mission Product*  
*Holdings Inc. v.*  
*Tempnology, LLC*

Feb 25: ICANN and the  
New Top-Level  
Domains

Mar 1: American  
University International  
Law Review  
Symposium - Hey  
Google, Tell Me About  
Privacy Policies  
Around the World

Mar 1: Sports and  
Entertainment Law  
Society Symposium

Mar 12: Copyright  
Limitations and  
Exceptions at WIPO

Mar 27: 9th Annual  
Patent Administrative  
Law Conference

Apr 15: IP at the  
Supreme Court Series  
- *Iancu v. Brunetti*

Apr 17: The Power of  
Coalitions - A Forum  
on Public Interest  
Intellectual Property  
Advocacy Honoring  
Prudence S. Adler

Apr 26: Frame the  
Lawyers - Annual Art  
Exhibit Opening  
Reception

[Full Event Archives](#)

## Trademark and Patent Works-in-Progress Colloquia

In September, PIJIP hosted the 8th Annual Trademark and Patent Works-in-Progress Colloquia, organized by Professors Christine Haight Farley and Jonas Anderson.

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## Alumni Networking event at Microsoft

PIJIP co-hosted our fifth annual networking reception at the Microsoft Innovation and Policy Center in downtown Washington, D.C. The event welcomed AUWCL students interested in intellectual property, alumni working in the field, and the law school's IP faculty. We were welcomed by Senior Director of Intellectual Property Policy at Microsoft and AUWCL alumna Susan Mann '86.

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## Rebecca Giblin: Moving Towards a New Copyright Bargain

Monash University Professor Rebecca Giblin's lecture proposed a new copyright bargain: one that, by taking authors' interests seriously, would simultaneously reclaim lost culture, promote access to knowledge and help authors get paid - all within those unamendable treaty frameworks.



---

## Margaret O'Mara: The Code

University of Washington Professor Margaret O'Mara gave a talk on her new book *The Code: Silicon Valley and the Remaking of America*. Her book describes the history of the tech industry in Silicon Valley as a nexus of entrepreneurship and government, new and old economies, far-thinking engineers and the many non-technical workers who made their innovation possible.

---

## Glushko-Samuelson IP Law Clinic

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### IP Clinic Welcomes Kathryn Kleiman

The Glushko-Samuelson Intellectual Property Law Clinic welcomes our new Practitioner-in-Residence, Kathryn Kleiman. She joins the clinic from Princeton University's Center for Information Technology Policy and the law firm of Fletcher, Heald and Hildreth, where she led the Internet Law & Policy Group. An expert on domain names, Kleiman was part of the group that founded ICANN, and she currently serves as co-chair of ICANN's Review of All Rights Protections Mechanisms Policy Development Process Working Group.

## Student Attorneys Provide IP Counseling for PBS Documentary "Look Who's Driving"

Intellectual Property Clinic student attorneys provided IP counseling on Kikim Media's new film *Look Who's Driving*, which aired on PBS in October. The program describes how autonomous vehicles are now being tested on public roads around the world, and describes the daunting challenges ahead, including how to train artificial intelligence to be even better than humans at making life-and-death decisions.

---

## Student Attorneys Submit Comment to FTC on Children's Online Privacy

Clinic students dove into voice-activated and EdTech technologies as part of their preparation of a response to the Federal Trade Commission's Request for Public Comment on the Implementation of the Children's Online Privacy Protection Rule.

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## Academic Program

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## National Jurist Gives IP Program an A+ for Intellectual Property

We received an A+ for Intellectual Property Law in rankings released in the Spring 2019 Edition of PreLaw Magazine. The grades were based on the breadth of the schools' curricular offerings in this specialty area. The program also was recently ranked #8 for Intellectual Property in the 2020 U.S. News and World Report rankings released March 12, 2019.

---

### Summer Sessions at American University and Geneva

Each summer, AUWCL's summer sessions include a broad selection of evening, weekend, and short courses. Students and practitioners gain insight into the ever-changing field of intellectual property law, including patent litigation, copyright fair use, fashion and design law, blockchain, multilateral law-making and dispute resolution at the WTO and WIPO, and much more.

Our Geneva Summer Program on International Organizations, Law and Diplomacy (PIOLD) offers students an in-depth look at international issues through direct contact with experts on intellectual property and international trade law at organizations such as WIPO and the WTO.

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## LLM in Intellectual Property

Every year, students from around the world come to AUWCL to study IP. They join more than 100 students from over 50 countries to study at one of the nation's top LL.M. (Masters in Law) programs.

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## Impact Projects

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## Activities of the Copyright User Rights Expert Network

### Advocating for Limitations and Exceptions at WIPO

PIJIP is one of a select group of non-governmental organizations that are accredited observers to the WIPO Standing Committee on Copyright and Related Rights (SCCR), the global policymaking body in copyright law. Observers have the opportunity to provide input at committee meetings. Led by PIJIP Director Sean Flynn, PIJIP coordinates the Global User Rights Network, which provides public-interest input at WIPO and to national governments undertaking copyright law reform. In March, PIJIP, Knowledge Ecology International and the Library Copyright Alliance co-hosted an event about the debate over copyright limitations and exceptions at the WIPO SCCR (pictured above).

### Supporting Copyright Reform in South Africa

In February 2019, PIJIP Professors Sean Flynn and Peter Jaszi submitted comments to the South African Parliament supporting copyright reform on behalf of the Network supporting copyright reform in South Africa. Flynn spoke on a South African copyright reform panel co-hosted by Wikipedia South Africa and ReCreate ZA in March; and on the panel "Decolonizing Copyright" in Johannesburg in August.

---

## Best Practices in Fair Use for Open Educational Resources

PIJIP and Creative Commons USA are working with creators to design a new *Code of Best Practices for the development of Open Educational Resources (OER)*. This project aims to evaluate the perception of copyright related barriers to the creation of OER that contain third party materials, such as quotations, excerpts, photographs and illustrations.

### PIJIP at Wikimania 2019

Professor Sean Flynn and Creative Commons USA Lead Meredith Jacob represented PIJIP at Wikimania 2019 in Stockholm, Sweden. Flynn organized a session on Copyright Advocacy Mapping, and Jacob co-hosted a session on Attribution: Laws, Norms, and Communicating to the Public.

---

## Fifth Global Congress on Intellectual Property and the Public Interest

PIJIP Hosted the Fifth Global Congress on Intellectual Property and the Public Interest in September 24, 2018. The Global Congress is the main convening of a global network of over 800 researchers, activists, and practitioners who work on the intersection of intellectual property and promotion of the public interest. The core goal is to promote evidence-based policy-making by fostering partnerships between academics and policy advocates from around the world.

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## Faculty Highlights

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Jonas Anderson



- *Patents Without the Right to Exclude*, 61 Wm. & Mary (forthcoming).
- *Empirical Scholarship of Claim Construction*, in 2 Research Handbook On The Economics Of Intellectual Property (Peter Menell & David Schwartz eds., 2019).

---

## Michael Carroll



- *Tailoring Intellectual Property Rights to Reduce Uniformity Cost*, in 1 Research Handbook On The Economics Of Intellectual Property (Ben Depoorter & Peter Menell eds., 2019).
- *Copyright and the Progress of Science: Why Text and Data Mining Is Lawful*, 53 U.C. Davis L. Rev. (forthcoming 2019).

---

## Christine Haight Farley



- *Public Policy Limitations on Trademark Subject Matter: A U.S. Perspective*, in Cambridge Handbook on International and Comparative Trademark Law (Irene Calboli & Jane Ginsburg eds., Cambridge University Press) (forthcoming 2020).
- *Confusing the Similarity of Trademark Law in Domain Name Disputes*, 52 Akron L. Rev. 607 (2019).

---

## Sean Flynn



- Comments of the Global Expert Network On Copyright User Rights to the South African National Council of Provinces on Copyright Amendment Bill [B13-2017]. (February 2019).
- Co-Chair, Committee on International Intellectual Property of the American Branch of the International Law Association.

---

## David Grossman





- *Future Technologies and Implications*, in *Sensor Management in ISR*, with W. Williamson. (Artech House, Norwood, Massachusetts) (forthcoming, 2020).
- U.S. Patent No. 10,257,499, "Motion Sensor," issued April 9, 2019, disclosing a device to optically track three-dimensional motion.

---

## Peter Jaszi



- *Code of Best Practices in Fair Use for Software Preservation*, with Patricia Aufderheide, Brandon Butler, and Krista Cox. (Center for Media and Social Impact, 2019).
- *Reclaiming Fair Use*, with Patricia Aufderheide. (U. Chicago Press, 2d ed., 2018).

---

## Kathryn Kleiman




- Co-chair, Review of All Rights Protections Mechanisms Policy Development Process Working Group of the Internet Corporation for Assigned Names and Numbers (ICANN).
- Panelist, American University Internet Governance Lab Discussion on Women, Technology & Change (November 2019).

---

## Victoria Phillips



- Keynote, *Innovation and Tradition: A Survey of Intellectual Property and Technology Legal Clinics*, (IP Clinic Faculty Workshop, Center for Intellectual Property Research, Indiana University Maurer School of Law, Bloomington, IN, September 2019).
  - *Innovation and Tradition: A Survey of Intellectual Property and Technology Legal Clinics*, 25 *Clinical L. Rev.* 95, with Cynthia L. Dahl (2018).
-



Program on Information Justice and Intellectual Pr  
4300 Nebraska Avenue  
Washington, DC District of Columbia  
United States

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**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 2/7/2020 8:28:58 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

b5

So you would need to advertise that. Let me know if I've misunderstood.

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31. 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, February 07, 2020 3:09 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

You may be right Misha. I can confirm with Dale.

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Sent:** Friday, February 7, 2020 3:07 PM  
**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Sent:** Friday, February 7, 2020 3:06 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

I was about to ask the same question.

b5

Bruce Goldstein, Esq., Director  
NHLBI Office of Technology Transfer & Development

REL0000025081

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, February 7, 2020 3:05 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Sent:** Friday, February 7, 2020 3:04 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, February 7, 2020 3:03 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

Ok. b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Sent:** Friday, February 7, 2020 3:01 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** NIHtoKEI re OcQuila 7Jan2020.docx

Dale, Mark, and Bruce – I realized I haven't yet responded to KEI's formal letter in response to our FR notice of intent to grant OcQuila an exclusive. b5

Please have a look at this response to KEI's letter so that I can send it out and clear this off my plate.

Thanks!

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
o. 301.435.5019  
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**Sent:** 4/28/2020 3:35:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Draft Response to KEI Objection  
**Attachments:** Response to KEI\_draft 4-28-20--OGCBerkleyComments.docx

Thanks got it finally, what do you think of these edits?

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, April 28, 2020 11:04 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Subject:** RE: Draft Response to KEI Objection

Open it with adobe

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Tuesday, April 28, 2020 10:49 AM  
**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: Draft Response to KEI Objection

Andy—I can't open the second file, the KEI response. Could you please resend?

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Sent:** Tuesday, April 28, 2020 10:23 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** Draft Response to KEI Objection

Hi Mark and Dale,

KEI's objection to my recent FR notice is attached, along with my draft response to the same. Please let me know if you have any questions or concerns.

Thank you,

Andy

REL0000025082

**Andrew R. Burke, Ph.D.**

Senior Technology Transfer Manager  
National Cancer Institute  
9609 Medical Center Drive, Rm 1E550  
Rockville, MD 20850

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**b5**



**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/7/2020 8:26:38 PM  
**To:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Okay, thank you both!

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
National Cancer Institute  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, February 7, 2020 3:26 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

**b5**

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, February 07, 2020 3:19 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

I propose

**b4,b5**

**b4,b5**

**From:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Sent:** Friday, February 7, 2020 3:11 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** FW: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Mark and Dale,

I received this follow up from KEI this afternoon. Let me know your thoughts on how I should respond.

Best,  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Friday, February 7, 2020 2:00 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Re: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Thank you, Dr. Freel.

1. Can you tell me the field of use for this license? In order for the public to exercise its right to comment, under 35 U.S.C. 209(e), it must have basic information about the license. The notice does not state the license's proposed field of use. Instead, it references the patent document, the text of which is not accessible to the public.

2. Your email pertains to the NCI's intent for granting the license, but it does not pertain to my questions regarding how the NCI determined that the license satisfies Section 209(a) in terms of granting exclusivity and the scope of the license. Those questions remain unanswered. We note that there is nothing precluding the NCI from answering them.

3. Why, in the NCI's view, are the terms of this license, including the duration of the license, business confidential?

4. Why, in the NCI's view, is the list of applicants for this license confidential?

5. Why will you not provide an estimate of the public's contribution, in federal funds, to the technology? We believe taxpayers have a right to know about their role in funding biomedical R&D. I understand that Stanford and CHOP co-developed the technology with the United States. They did not develop it alone, however. We seek to better understand the NCI's contribution to the technology. I believe that is not an unreasonable ask.

I look forward to working with you to gain a better understanding of this license and the NCI's analysis.

Sincerely,  
Kathryn Ardizzone

On Fri, Feb 7, 2020 at 12:45 PM Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)> wrote:

Dear Kathryn,

REL0000025084

Regarding your separately emailed question about the press release from CHOP, that press release is related to a different technology that is the subject of a separate patent family.

This invention is at the preclinical stage of development and therefore, no clinical trials have commenced. The invention was jointly developed between researchers at the NCI, Stanford and CHOP and is co-owned by the three institutions. The contemplated license is for the purpose of consolidating rights of the three co-owners to allow Stanford to take the lead on behalf of all the co-owners. The intention of the prospective license is to expedite the commercial development of the invention.

The remainder of your questions have either been asked on previous prospective licenses and the answers for this license are the same or they are not relevant to the criteria for granting an exclusive license. The terms for this license are not yet determined as this license is not yet completed. Our license templates are readily available to the public, however, the specific terms related to this license are business confidential.

Best Regards,

Rose

--

Rose Santangelo Freel, Ph.D.

Senior Technology Transfer Manager

**National Cancer Institute**

P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Thursday, February 6, 2020 4:07 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Subject:** Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Ms. Freel:

REL0000025084

At your earliest convenience, please answer the following questions regarding "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2":

1. What is the development stage of the invention? Have any clinical trials investigating it commenced? If so, what are their numbers?
2. What was the NCI's role in developing the invention, and how does it relate to that of Stanford and CHOP?
3. Please provide an estimate of what the NCI has spent in developing the invention, and list any grant numbers associated with it.
4. What is the proposed duration of the license?
5. On what basis did the NIH conclude that an exclusive patent license is a necessary incentive?
6. How will the NIH limit the scope of the license to not broader than the necessary incentive?
7. How will the NIH share in any royalties paid by a sublicensee to Stanford? 8. How will the license ensure that NIH receives a reasonable return on its investment in the invention?
9. Has the NIH sought the antitrust advice of the U.S. Attorney General concerning the license?

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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**From:** Wong, Jennifer A (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6603ED16C184B8B83F02F5FA40A05DF-WONGJA]  
**Sent:** 11/13/2019 8:02:19 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Predescu, Alina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a60e98376e746c7a37640bd40f45149-predescuad]  
**Subject:** RE: Kite and Intima appeals from KEI

Hi, Mark. Alina and I took a look at this. The letters from KEI looked very similar so we decided to go over both letters together.

Broadly speaking, [REDACTED] b5 Also, Alina  
and I noted that: [REDACTED] b5  
[REDACTED] b5

Below are observations regarding your request to review the draft correspondence:

[REDACTED] b5

Alina and Jennifer

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, November 12, 2019 12:19 PM  
**To:** Predescu, Alina (NIH/OD) [E] <alina.predescu@nih.gov>; Wong, Jennifer A (NIH/OD) [E] <wongja@od.nih.gov>  
**Subject:** FW: Kite and Intima appeals from KEI

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, November 12, 2019 12:12 PM  
**To:** Predescu, Alina (NIH/OD) [E] <alina.predescu@nih.gov>; Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>  
**Subject:** FW: Kite and Intima appeals from KEI

COULD YOU DO THIS TODAY AND TOMORROW? This is a draft response to the 2 appeals (attached) from KEI regarding their objections to particular licenses. Could each of you take one of these and refer to the draft letter to (1) make sure the major KEI points are addressed in the draft and (2) the draft is clearly written. Thanks.

---

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Thursday, November 7, 2019 11:58 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>

REL0000025086

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** Kite and Intima appeals from KEI

Mark:

The attached draft letter to KEI

b5

b5

I've attached the source documents (sans attachments) for your convenience.

Let me know what you think.

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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REL0000025086

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 4/28/2020 2:22:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** Draft Response to KEI Objection  
**Attachments:** Response to KEI\_draft 4-28-20.docx; KEI Objection\_4-17-20

Hi Mark and Dale,

KEI's objection to my recent FR notice is attached, along with my draft response to the same. Please let me know if you have any questions or concerns.

Thank you,

Andy

**Andrew R. Burke, Ph.D.**

Senior Technology Transfer Manager  
National Cancer Institute  
9609 Medical Center Drive, Rm 1E550  
Rockville, MD 20850

Direct: (240) 276-5484

Email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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**b5**



1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

April 17, 2020

Andrew Burke, Ph.D.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive  
Bethesda, MD 20892-9702  
Via Email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

**Re: Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy**

Dear Dr. Burke:

Knowledge Ecology International (KEI) and Union for Affordable Cancer Treatment (UACT) are writing to comment on the "Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy" to Lyell Immunopharma, Inc. ("Lyell").<sup>1</sup> The proposed license encompasses six inventions related to adoptive cell therapy for indications "in cancer in humans." A former National Institutes of Health (NIH) scientist who co-invented all six inventions in his capacity as an NIH employee is an executive officer with Lyell who joined in July 2019.

With the NIH proposing to grant Lyell a monopoly over six taxpayer-funded inventions that may improve adoptive cell therapies for terminal cancer, in all forms of cancer in humans, the terms of the license regarding pricing and affordability and years of exclusivity are of great importance to cancer patients and to anyone who is responsible for paying the costs of the treatments.

The NIH may not grant the license unless all the criteria listed at 35 U.S.C. § 209(a) have been satisfied.

We object to the license for the following reasons:

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<sup>1</sup> 85 Fed. Reg. 18577, available at

<https://www.federalregister.gov/documents/2020/04/02/2020-06922/prospective-grant-of-an-exclusive-patent-license-methods-and-compositions-for-adoptive-cell-therapy>.

1. The NIH apparently has not analyzed whether exclusivity is a reasonable and necessary incentive or limited the scope of the license to not broader than necessary, as required by 35 U.S.C. § 209(a)(1)-(2);
2. The NIH has not been transparent about the license, refusing to answer six out of nine questions submitted by KEI, and limiting our ability to comment on the license, which is guaranteed by 35 U.S.C. § 209(e); and
3. The NIH has not sought the antitrust advice of the U.S. Attorney General with respect to the license, as required by 40 U.S.C. § 559.

If the NIH grants the license over our objections, we request that the license incorporates a series of provisions designed to safeguard the public interest in the technologies and promote the policies outlined in the Public Health Service (PHS) Technology Transfer Manual.

## **Background**

### *The Inventions*

The proposed license covers six publicly-owned inventions grouped into three categories: Group A, Group B, and Group C. Group A contains a method of identifying the cancer patients who are likely to respond to adoptive cell therapy. Groups B and C contain methods of generating T-cells that may be able to overcome some of the limitations in current cell therapies.

According to articles reporting the inventions, the following NIH grants funded the research underlying the subject technology:

- ZIA BC010763, FYs 2009 to 2019, for a total of \$54,856,083;
- K08 CA197966, FYs 2015 to 2019, for a total of \$874,800; and
- ZIA BC011480, FYs 2013 to 2019, for a total of \$7,351,653.

Because we do not know when each invention was finalized, it is possible that not all of the funded years of the grants listed above supported the research behind the subject inventions. We asked Dr. Andrew Burke, the point of contact for the license, how much federal funding contributed to the inventions, and he did not answer. We would be able to report more specific information regarding funding of inventions if the NIH improved its reporting mechanisms and were more transparent about the role of public funding in federally-funded inventions.

### *The Prospective Licensee*

The prospective licensee, Lyell, is a biotech company founded by Rick Klausner, the former head of the National Cancer Institute (NCI), a former executive director for global health at the Bill and Melinda Gates Foundation, and a co-founder of Juno Therapeutics.<sup>2</sup>

Nicholas Restifo, one of the inventors of all six inventions covered by the license, is Executive Vice President, Research for Lyell. Restifo helped conceptualize the inventions while funded by an NIH grant, ZIA BC010763, which awarded a total of \$54,856,083 to fund his research from 2009 to 2019. Restifo joined Lyell in July of 2019.

Lyell's website contains little information other than a short description of the company and biographies of its executive officers. The webpages for "Press Releases," "Publications," and "News," direct viewers to check back later for updates.

Lyell's business model appears to be focused on developing technologies to make adoptive T-cell therapies more effective and licensing them to biotech companies with immunotherapies in their pipeline.

In October of 2019, Lyell entered into a five-year collaboration with GlaxoSmithKline (GSK) in which Lyell will contribute its technologies to improve the T-cell performance of GSK's cell therapy products.<sup>3</sup>

On March 17, 2020, Eureka Therapeutics, Inc., "a clinical stage biotechnology company developing novel T cell therapies for solid tumors," announced that the company had entered into a "strategic collaboration" with Lyell "to develop therapies against several undisclosed solid tumor targets expressed across multiple cancer types."<sup>4</sup> Lyell's role in the partnership is "to improve the efficacy of engineered T cells in solid tumors."<sup>5</sup>

## Discussion

### 1. The NIH apparently has not meaningfully applied the statutory criteria governing exclusive licenses.

The NIH's technology transfer policy favors nonexclusive licenses, and exclusive licenses may not be granted unless all of the criteria listed at 35 U.S.C. § 209 are satisfied.<sup>6</sup> These criteria

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<sup>2</sup>

<https://endpts.com/exclusive-gsks-hal-barron-allies-with-rick-klausners-600m-cell-therapy-startup-looking-to-break-new-ground-blitzing-solid-tumors/>.

<sup>3</sup>

<sup>4</sup> <https://www.eurekatherapeutics.com/media/press-releases/031720/>.

<sup>5</sup> *Id.*

<sup>6</sup> PHS Technology Transfer Policy Manual Chapter No. 305, "PHS Policy for Making Determinations Regarding the Grant of Exclusive or Partially Exclusive Commercialization Licenses." <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/305-policy.pdf>.



include that exclusivity is a reasonable and necessary incentive to enable the commercialization of the subject technology, and that the scope of the license is not broader than necessary.<sup>7</sup>

The NIH's correspondence with KEI regarding this license appears to indicate that the NIH has failed to give meaningful consideration to the statutory criteria.

KEI asked Dr. Burke how the NIH determined that an exclusive license to the subject inventions is a reasonable and necessary incentive, and that the scope of the license is not broader than necessary. He declined to answer, stating that the question had already been answered, and referring KEI to NIH's past answers to unrelated licensing decisions.

The NIH's past statements regarding how it applies 35 U.S.C. § 209(a)(1) to exclusive patent licenses indicate that the NIH grants an exclusive license whenever doing so will promote commercial development. As KEI has explained in previous comments, that policy violates the statutory standard, which allows exclusivity only when it is necessary and not when it is merely helpful.

In order to conclude that an exclusive license is necessary, some analysis must be undertaken, including, for example, consideration of the other types of incentives provided by law, such as test data protection, Orphan Drug exclusivity, etc., and the likely case that the developer can bring other patented inventions into the project, for which exclusivity exists. The NIH's statements indicate that no such analysis has been performed. As Dr. Mark Rohrbaugh, Senior Advisor for Technology Transfer, has stated to KEI, the NIH assumes that exclusivity is necessary, because it "works in a market for these early-stage therapeutic technologies in which there is essentially no demand for nonexclusive licenses."

Similarly, the NIH's past statements regarding the scope of a license indicate that it does not properly apply the statutory criteria.

The scope of an exclusive license must "not [be] greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" 35 U.S.C. § 209(a)(2).

The scope of an exclusive patent license may vary in terms of the period of exclusivity, territorial reach, and field of use, among other parameters. Each license requires individualized consideration to determine the appropriate scope.

The fields of use for the license and its territorial scope are extremely broad. According to the Federal Register Notice, the fields of use "may be limited to":

- "Manufacture and commercialization of companion diagnostics approved or cleared by the FDA . . . for Licensee-proprietary T cell therapy products" (Group A);

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<sup>7</sup> 35 U.S.C. § 209(a)(1)-(2).

- “Manufacture and commercialization of adoptive T cell therapy products generated from autologously-derived, induced pluripotent stem cells for the treatment of cancer in humans” (Group B); and
- “Manufacture and commercialization of adoptive T cell therapy products isolated from peripheral blood for the treatment of cancer in humans” (Group C).

The proposed territorial reach of the license is “worldwide.”<sup>8</sup>

In testimony explaining NIH licensing practices to Congress, Dr. Rohrbaugh described how the field of use for a license can be narrowed as follows:

[M]ultiple aspects of a single technology may be exclusively licensed to multiple parties. For example, a technology for treating a variety of cancers might be licensed to one company for lung cancer therapeutics and to another for liver and pancreatic cancer therapeutics.<sup>9</sup>

The field of use should be narrowed further so that it would not embrace all cancer in humans, which is overbroad.

The NIH surely must know that companies that develop such technologies routinely enter into contracts that limit exclusivity in other ways as well, for example, granting exclusivity in some markets, but not others. The United States could grant exclusivity to the European Union, Japan and other high income countries, but not to the United States, for example, so that countries that did not fund the R&D would bear the costs of the exclusivity, while U.S. residents would not. And the U.S. could limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.

The NIH could also grant exclusivity for a period less than the term of the patent, or only until a company achieved a certain level of global revenue from sales.

The NIH has stated, however, that it generally does not limit the duration of its exclusive patent licenses, because “companies and investors . . . require an exclusive license for the full patent term.”

If the NIH did not investigate the possibility of limiting the term of the proposed license, or using non-US high income countries only for the exclusivity, it has not satisfied its obligations under 35 U.S.C. § 209(a)(1)-(2).

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<sup>8</sup> *Id.*

<sup>9</sup> Mark L. Rohrbaugh, “NIH: Moving Research from the Bench to the Bedside, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health,” July 10, 2003, available at <https://www.govinfo.gov/content/pkg/CHRG-108hhrg88429/html/CHRG-108hhrg88429.htm>.

2. The NIH was not transparent about the license, limiting the public's right to comment under 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely-submitted comments. 35 U.S.C. § 209(e).

The NIH has not been transparent about the license, impeding our ability to exercise the right to comment guaranteed by 35 U.S.C. § 209(e).

For the public to meaningfully comment on a proposed license, it must have basic information about it. Our ability to comment on the license has been limited by the NIH's refusal to answer six of the nine questions that KEI submitted to Dr. Burke. Rather than answering the questions, Dr. Burke stated that the questions have already been answered, and referred KEI to those supposed past answers. Of course, Dr. Burke's statement was not and could not be true. KEI's list of questions was specific to the instant license, about which KEI had never previously inquired. KEI pointed that out to Dr. Burke, in a follow-up email, but he never responded.

In the past, the NIH has asserted two main reasons for refusing to answer KEI's questions: 1) that the information sought was irrelevant and 2) that the information was confidential. Neither assertion is true.

The questions Dr. Burke refused to answer related to how the NIH had applied the criteria at 35 U.S.C. § 209 governing a federal agency's authority to grant an exclusive license. There can be no issue more directly relevant to a licensing decision than how the NCI determined that an exclusive license was a reasonable and necessary incentive (35 U.S.C. § 209(a)(1)) and how it concluded that the scope of the license is not broader than necessary (35 U.S.C. § 209(a)(2)). Yet these are two of the questions Dr. Burke failed to answer.

Nor was the information that Dr. Burke refused to answer confidential business information.

The NIH has stated that it cannot answer many of KEI's questions about its licensing practices because NIH "has a duty to safeguard" confidential information contained in license applications, such as "proposed commercial plans, including earnings, proposed expenditures, and trade secret information."

KEI did not request any sensitive information contained in a license application. For example, one question KEI asked, and Dr. Burke refused to answer, was which, if any, other companies have submitted an application for the license.



Federal law and regulations regarding government patent licenses do not make all aspects of license applications confidential. Rather, they establish the confidentiality only of a license applicant's commercialization plans and periodic utilization reports. The identity of an applicant for a license is not a commercialization plan or periodic utilization report.

The Bayh-Dole Act appropriately gives the public a role in licensing decisions concerning inventions that are funded and owned by the public. Because the questions KEI asked and Dr. Burke refused to answer were relevant and non-confidential, Dr. Burke had no basis for refusing to answer them and undermined our ability to comment on the license.

3. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

We object to the license because the NIH has not first obtained the antitrust advice of the United States Attorney General.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property.” The statute exempts personal property if the fair market value is less than \$3,000,000, but specifically excludes “a patent, process, technique, or invention” from that exception.

The regulation 41 C.F.R. § 102-75.270 also makes clear the inclusion of patents “irrespective of cost.”

KEI asked Dr. Burke whether the NIH requested the advice of the U.S. Attorney General concerning the licenses. Dr. Burke did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.

We disagree.

35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to



convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

The term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants an exclusive license in a federally-owned invention, it is disposing of a government property interest so as to trigger 40 U.S.C. § 559.

4. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public’s interest in the NIH-funded technology:

1. **Exclusivity.** If the NIH decides to grant exclusive rights to the subject inventions, it should limit exclusivity to the European Union, Japan and other high-income countries, but not the United States, so that countries that did not fund the R&D underlying the inventions would bear the costs of the exclusivity, while the U.S. residents would not. The NIH should also limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.
2. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
3. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”

4. **Global registration and affordability.** The license should require Lyell Immunopharma to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
5. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
6. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”
7. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

## **Conclusion**

We object to the proposed license to Lyell for the reasons stated herein. In the event that the NIH grants the license, we ask that it incorporates the provisions listed above, which are designed to protect the public interest in the licensed technologies and to accomplish the policies outlined in the PHS Technology Transfer Manual.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment

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**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 11/12/2019 6:48:37 PM  
**To:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** KEI Appeal Letter

Good afternoon Dale and Mark,

I wanted to check in to see if you have sent the letter to KEI denying their appeals to the grant of licenses under A-366-2019 and A-367-2019. The applicant is asking for an update.

Thanks,  
Dave

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**From:** Fenn, Tedd (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B0F88C66575C49FB9F70456838521059-FENNEA]  
**Sent:** 11/8/2019 3:58:15 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]  
**Subject:** FW: Cell Ray, LLC

Hi Mark,  
KEI seems to be trying a less formal approach.  
My proposed responses are in red.

I am not sure about the last question —

b5

b5

-Tedd

**From:** James Love <james.love@keionline.org>  
**Sent:** Saturday, November 2, 2019 11:52 AM  
**To:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>  
**Cc:** Claire Cassedy <claire.cassedy@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>  
**Subject:** Cell Ray, LLC

<https://www.federalregister.gov/documents/2019/11/04/2019-23995/prospective-grant-of-an-exclusive-patent-license-for-autologous-cell-graft-of-manufactured-retinal>

Tedd,

can you tell us what Cell Ray LLC is?

b5

b5

I don't see a web page.

Can you tell us who is on the Board of Directors, and who is the senior staff?

b5

b5

Also, can you tell us the stage of the development of this invention,

b5

and who at the NIH we can talk to about the technology?

Jamie

--

James Love. Knowledge Ecology International  
U.S. Mobile +1.202.361.3040  
U.S. office phone +1.202.332.2670  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000025090



**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 2/7/2020 8:05:51 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, February 7, 2020 3:05 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Friday, February 7, 2020 3:04 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, February 7, 2020 3:03 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE: NIHtoKEI re OcQuila 7Jan2020.docx

Ok.

b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Friday, February 7, 2020 3:01 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** NIHtoKEI re OcQuila 7Jan2020.docx

Dale, Mark, and Bruce – I realized I haven't yet responded to KEI's formal letter in response to our FR notice of intent to grant OcQuila an exclusive. b5

Please have a look at this response to KEI's letter so that I can send it out and clear this off my plate.

Thanks!

REL0000025094

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development

31 Center Drive Room 4A29, MSC2479

Bethesda, MD 20892-2479

o. 301.435.5019

[shmilovm@nih.gov](mailto:shmilovm@nih.gov)

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REL0000025094

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 10/1/2019 4:54:51 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW:  
**Attachments:** Declaration by Mark L. Rohrbaugh\_v2 01082019.pdf

Hi Mark,

b5

Thanks,

Andy

**From:** Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>  
**Sent:** Thursday, September 26, 2019 2:11 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** FW:

Mark's Declaration for the lawsuit: b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 24, 2019 5:58 PM  
**To:** Vathyam, Surekha (NIH/NCI) [E] <vathyams@mail.nih.gov>  
**Subject:**

See attached Declaration from the KEI v. NIH case.

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health



**b5**

**b5**

**b5**

---

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/27/2020 2:55:34 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: KEI, UACT Comments re Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Good morning Mark,

I am following up on my e-mail from last Tuesday since I have not heard back. Please let me know if we have clearance to send out the letter I drafted at your earliest convenience. If you need me to resend it, let me know.

Thanks,

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

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**From:** Lambertson, David (NIH/NCI) [E]  
**Sent:** Tuesday, April 21, 2020 3:58 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** FW: KEI, UACT Comments re Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Good afternoon Mark,

KEI submitted the attached objection (the PDF) to the grant of an exclusive license; please note this is subsequent to their questions, which we discussed last week. I attach a proposed response to their objection (word document), which is similar in content to previous replies to their official objections. Please let me know if you believe any additions, subtractions or other modifications would be beneficial to the response. I look forward to your response.

Thanks,

David A. Lambertson, Ph.D.

REL0000025096

Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

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Fax: 240-276-5504

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**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Friday, April 17, 2020 3:53 PM  
**To:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; manon.ress@cancerunion.org  
**Subject:** KEI, UACT Comments re Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

Attached are the comments of Knowledge Ecology International and Union for Affordable Cancer Treatment regarding "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer."

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** Knezevic, Vlado (NIH/NIDDK) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CD7FD096830401C88A2C03EC1916B3C-KNEZEVICV2]  
**Sent:** 4/24/2020 2:43:27 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Niebylski, Charles (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3248b0e1497e439b94ce47c2f52b0268-niebylskicd]  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Thank you Mark – once response goes back to them, are we require to wait for their response?  
Are we required to engage in further exchanges?

Chuck – I will prepare draft response for your review.  
Thanks,

*Vlado*

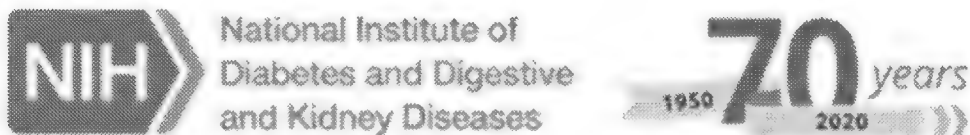
---

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation

Technology Advancement Office (TAO)  
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)  
National Institutes of Health  
Department of Health & Human Services  
Building 12A, Room 3011  
Bethesda, MD 20817-5632  
Office phone: 301-435-5560  
Mobile: [REDACTED]  
Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

[www.niddk.nih.gov](http://www.niddk.nih.gov)



---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, April 24, 2020 10:42 AM  
**To:** Niebylski, Charles (NIH/NIDDK) [E] <[charles.niebylski@nih.gov](mailto:charles.niebylski@nih.gov)>  
**Cc:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Thanks Chuck. We have been handling them now by answering the first 2 questions if you have that information. For the others, you can respond by saying: The other questions are either not relevant to the criteria for granting an exclusive license or are questions that have been answered by NIH previously.

---

**From:** Niebylski, Charles (NIH/NIDDK) [E] <[charles.niebylski@nih.gov](mailto:charles.niebylski@nih.gov)>  
**Sent:** Friday, April 24, 2020 10:37 AM

REL0000025098

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Cc:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>

**Subject:** FW: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Hi Mark,

I trust all is well. We just had a FRN posted for a notice of intent to negotiate an exclusive license for an NIDCR technology. KEI sent us the following request for information. Please advise on how Building 1 wishes us to handle such a request from KEI.

Thanks, Chuck

**Charles Niebylski, PhD JD**

Director

Technology Advancement Office (TAO)

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)

National Institutes of Health

Department of Health & Human Services

Building 12A, Room 3011

Bethesda, MD 20817-5632

Ph: 301-435-8146

[nibs@nih.gov](mailto:nibs@nih.gov)

**From:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>

**Sent:** Friday, April 24, 2020 10:17 AM

**To:** Niebylski, Charles (NIH/NIDDK) [E] <[charles.niebylski@nih.gov](mailto:charles.niebylski@nih.gov)>

**Subject:** FW: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Here we go.....now we need to talk.....

KEI in action. This is in regard to Kriya exclusive license FRN posting.

*Vlado*

---

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation

Technology Advancement Office (TAO)

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)

National Institutes of Health

Department of Health & Human Services

Building 12A, Room 3011

Bethesda, MD 20817-5632

Office phone: 301-435-5560

Mobile: **b6**

Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

[www.niddk.nih.gov](http://www.niddk.nih.gov)

REL0000025098

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Friday, April 24, 2020 9:59 AM

**To:** Knezevic, Vlado (NIH/NIDDK) [E] <vlado.knezevic@nih.gov>

**Subject:** Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Dear Dr. Knezevic:

Please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity":

1. At what stage of research and development is the invention?
2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?
3. Please estimate how much the NIH has spent to develop the inventions.
4. On what basis did the NIH conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?
  - a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?
  - b. Did you estimate the cost of bringing the technologies to market?
5. How many years will the license be exclusive?
6. How has the NIH determined that the scope of the license is not broader than necessary?
7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?
8. Please provide a list of the firms that applied to license each of the covered inventions.

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 11/7/2019 4:49:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: Response to KEI re A-506-2019

Hi Mark,

I will add some additional detail to letter along the lines you recommend. The response already states that: **b5**

**b5**

I would also like to

**b5**

**b5**

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, November 6, 2019 11:26 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** FW: Response to KEI re A-506-2019

Andy, **b5**

**b5**

Thanks

**From:** "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>  
**Date:** November 6, 2019 at 9:59:13 AM EST  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Subject:** RE: Response to KEI re A-506-2019

Hi Mark,

This is addressed at length in the final determination. **b5**

**b5**

**b5**

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, November 6, 2019 9:55 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: Response to KEI re A-506-2019

Thanks Andy. Given their comments about exclusivity, I think the response should include: **b5**

**b5**

**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Sent:** Wednesday, November 6, 2019 9:42 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: Response to KEI re A-506-2019

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, November 5, 2019 5:41 PM  
**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Subject:** RE: Response to KEI re A-506-2019

Can you send me their comments? Thx

**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Sent:** Tuesday, November 5, 2019 3:17 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** Response to KEI re A-506-2019

Hi Mark,

Richard signed the final determination for the above-referenced exclusive license application today, so I've prepared a response to KEI's objection (attached). Please let me know if you have any question or concerns.

Thank you,

Andy

**Andrew R. Burke, Ph.D.**  
Senior Technology Transfer Manager  
National Cancer Institute  
9609 Medical Center Drive, Rm 1E550  
Rockville, MD 20850

Direct: (240) 276-5484  
Email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

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**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/7/2020 1:52:07 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: KEI Questions - IIA FR Notice

Thanks Mark! See below for my draft email. Please let me know your thoughts.

Dear Kathryn,

b5

Best Regards,  
Rose

--  
Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
National Cancer Institute  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Thursday, February 6, 2020 6:03 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: KEI Questions - IIA FR Notice

You could

b5

b5

And then something like:

b5

b5

Please provide me with the draft before sending. Thanks.

REL0000025102

**From:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>

**Sent:** Thursday, February 6, 2020 4:43 PM

**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>

**Subject:** KEI Questions - IIA FR Notice

Hi Dale and Mark,

I've received questions from KEI regarding the FR notice for the IIA with Stanford (linked below). For the press release question with CHOP, [REDACTED] b5

b5

For the list of 9 questions, [REDACTED] b5

b5

<https://www.federalregister.gov/documents/2020/01/24/2020-01154/prospective-grant-of-exclusive-patent-license-antibody-based-therapeutics-and-chimeric-antigen>

Best Regards,  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
**National Institutes of Health**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

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REL0000025102

**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/6/2020 9:43:11 PM  
**To:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrgr]  
**Subject:** KEI Questions - IIA FR Notice  
**Attachments:** Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2; Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Dale and Mark,

I've received questions from KEI regarding the FR notice for the IIA with Stanford (linked below). For the press release question with CHOP,

b5

For the list of 9 questions,

b5

b5

b5

<https://www.federalregister.gov/documents/2020/01/24/2020-01154/prospective-grant-of-exclusive-patent-license-antibody-based-therapeutics-and-chimeric-antigen>

Best Regards,  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
**National Institutes of Health**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

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REL0000025104

---

**From:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**Sent:** 2/6/2020 9:06:45 PM  
**To:** Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]  
**Subject:** Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Ms. Freel:

At your earliest convenience, please answer the following questions regarding "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2":

1. What is the development stage of the invention? Have any clinical trials investigating it commenced? If so, what are their numbers?
2. What was the NCI's role in developing the invention, and how does it relate to that of Stanford and CHOP?
3. Please provide an estimate of what the NCI has spent in developing the invention, and list any grant numbers associated with it.
4. What is the proposed duration of the license?
5. On what basis did the NIH conclude that an exclusive patent license is a necessary incentive?
6. How will the NIH limit the scope of the license to not broader than the necessary incentive?
7. How will the NIH share in any royalties paid by a sublicensee to Stanford?
8. How will the license ensure that NIH receives a reasonable return on its investment in the invention?
9. Has the NIH sought the antitrust advice of the U.S. Attorney General concerning the license?

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**Sent:** 2/6/2020 8:24:19 PM  
**To:** Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]  
**Subject:** Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Ms. Freel:

At your earliest convenience, can you please confirm whether the above-titled Federal Register notice pertains to the "antibody-drug conjugate (ADC) called D3-GPC2-PBD" developed by researchers at the National Cancer Institute, per this [CHOP press release](#)?

Thank you in advance,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Prabhu, Yogikala (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6DC0FA019B424F05B6F86D734D5B894A-PRABHUYO]  
**Sent:** 2/4/2020 8:18:09 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Tung, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=673ea50c713a457f82e4c3ecbf361d03-tungpp]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Attachments:** KEI Comments, "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)"; KEI Comments re Exclusive Patent License in Regulatory T-cells for Treatment of Hemophilia A to Teralmmune, Inc. .pdf

Dear Mark,

Thank you very much for your review and comments. However, we received a formal letter from KEI (please see attached). Kindly let us know your thoughts/suggestions.

Best Regards,  
Yogi

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, February 4, 2020 1:18 PM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <yogikala.prabhu@nih.gov>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Tung, Peter (NIH/NIAID) [E] <peter.tung@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

Thanks for sending this. I have proposed edits attached,

b5

b5

Happy to answer questions.  
Regards,  
Mark

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <yogikala.prabhu@nih.gov>  
**Sent:** Monday, February 3, 2020 11:42 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

REL0000025106



**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dear Mark,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!  
Best Regards,  
Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Monday, February 3, 2020 11:37 AM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

You need to forward this to Mark and copy me.

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Sent:** Monday, February 03, 2020 11:24 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>

**Subject:** KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

**Importance:** High

Dear Dale,

We have received questions from KEI regarding the Federal Register Notice 2020–00721, entitled “*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*,” published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!

Best Regards,

Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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REL0000025106

---

**From:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**Sent:** 2/4/2020 3:51:31 AM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc0fa019b424f05b6f86d734d5b894a-prabhuyo]  
**CC:** James Love [james.love@keionline.org]  
**Subject:** KEI Comments, "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)"  
**Attachments:** KEI Comments re Exclusive Patent License in Regulatory T-cells for Treatment of Hemophilia A to TeraImmune, Inc. .pdf

Dear Dr. Prabhu:

Attached, please find Knowledge Ecology International's comments regarding Prospective Grant of Exclusive Patent License: Development of Regulatory T-cells for Treatment of Hemophilia A (HA)."

Thank you in advance.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 9/26/2019 7:04:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Final Response to KEI Objection  
**Attachments:** Response to KEI K Ardizzone Comments\_draft 9-26-19.docx

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, September 26, 2019 2:38 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: Final Response to KEI Objection

Please send me the final.

**From:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Sent:** Thursday, September 26, 2019 1:46 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Final Response to KEI Objection

Hi Mark,

I deleted that sentence from the letter. I know that

b5

b5

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, September 26, 2019 1:39 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: Final Response to KEI Objection

Thanks Andy,  
suggest

b5

I would

b5

b5

**From:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Sent:** Thursday, September 26, 2019 1:26 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** Final Response to KEI Objection

Hi Mark,

Attached is my draft response to the formal objection KEI submitted on September 13. Please let me know if you have any questions or concerns.

Thank you,

REL0000025108

Andy

**Andrew R. Burke, Ph.D.**

Senior Technology Transfer Manager  
National Cancer Institute  
9609 Medical Center Drive, Rm 1E550  
Rockville, MD 20850

Direct: (240) 276-5484

Email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI  
9609 Medical Center Drive, Suite 530  
Rockville, MD 20852  
Office (240) 276-5530  
Facsimile (240) 276-5504

**b5**

---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 2/4/2020 6:09:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

I'm fine with this Mark, thanks.

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, February 04, 2020 11:53 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** FW: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dale:

Could you please give this a quick review. In the attached email, KEI asked 8 questions.

b5

b5  
text?

Do you any concerns or suggestions for the

Thanks,  
Mark

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Sent:** Monday, February 3, 2020 11:42 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dear Mark,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!  
Best Regards,  
Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**

REL0000025110

## Technology Transfer and Patent Specialist

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Monday, February 3, 2020 11:37 AM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

You need to forward this to Mark and copy me.

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Sent:** Monday, February 03, 2020 11:24 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>  
**Subject:** KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dear Dale,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!  
Best Regards,  
Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**



**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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---

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/21/2020 7:58:10 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** FW: KEI, UACT Comments re Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer  
**Attachments:** KEI, UACT Comments re License, Bispecific Anti-GPC1 Antibodies to NeoImmune Tech, Inc..pdf; A-199-2020\_Response to KEI.docx

Good afternoon Mark,

KEI submitted the attached objection (the PDF) to the grant of an exclusive license; please note this is subsequent to their questions, which we discussed last week. I attach a proposed response to their objection (word document), which is similar in content to previous replies to their official objections. Please let me know if you believe any additions, subtractions or other modifications would be beneficial to the response. I look forward to your response.

Thanks,

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
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**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, April 17, 2020 3:53 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Cc:** James Love <james.love@keionline.org>; manon.ress@cancerunion.org  
**Subject:** KEI, UACT Comments re Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

Attached are the comments of Knowledge Ecology International and Union for Affordable Cancer Treatment regarding "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer."

Sincerely,

REL0000025111

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



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Suite 500  
Washington, DC 20009  
[www.keionline.org](http://www.keionline.org)

April 17, 2020

David Lambertson, Ph.D.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive  
Bethesda, MD 20892-9702  
Via Email: [david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)

**Re: Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer**

Dear Dr. Lambertson:

Knowledge Ecology International (KEI) and Union for Affordable Cancer Treatment (UACT) are writing to comment on the "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer" to Neolmmune Tech, Inc. ("Neolmmune").<sup>1</sup>

During the comment period, KEI asked the National Institutes of Health (NIH) several questions about the license. The NIH has not answered any of the questions submitted by KEI, thereby limiting our ability to comment on the license, a right that is provided in 35 U.S.C. § 209(e).

Because the license disposes of government-owned property, the NIH may not grant the license unless it first requests the antitrust advice of the U.S. Attorney General. 40 U.S.C. § 559.

If the NIH grants the license, we request that it incorporates a series of provisions designed to safeguard the public interest in the invention and promote the policy objectives of the Public Health Service (PHS) Technology Transfer Manual.

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<sup>1</sup> 85 Fed. Reg. 18579, available at

<https://www.federalregister.gov/documents/2020/04/02/2020-06917/prospective-grant-of-an-exclusive-patent-license-the-development-of-bispecific-antibodies-targeting>.

## Background

The proposed license involves one invention, E-028-2019, "High Affinity Monoclonal Antibodies Targeting Glypican-1" (U.S. Patent Application No. 62/795,415).

According to the Federal Register notice, the field of use for the license "[m]ay be limited to: The research, development and commercialization of a bispecific antibody or the treatment of GPC1-expressing human cancers."

The license opportunity notice for the invention states that it has "[p]otential therapeutic benefit for several cancer types with few treatment options – including uterine cervical cancer and pancreatic adenocarcinoma[.]"<sup>2</sup>

The prospective licensee, NeoImmune, is a biotech company based in Rockville, Maryland, with a location in Korea. NeoImmune's lead product is Hyleukin-7, a "T cell amplifier designed to reconstitute and enhance antitumoral T cell immunity."<sup>3</sup>

## Discussion

### 1. The NIH was not transparent about the license, limiting the public's right to comment under 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely-submitted comments. 35 U.S.C. § 209(e).

For the public to meaningfully comment on a proposed license, it must have basic information about it. Our ability to comment on the license has been limited by the NIH's refusal to answer all of the questions that KEI submitted to the NIH.

On April 13, 2019, KEI emailed Dr. David Lambertson, the point of contact for the license, a list of nine questions about it. He did not respond prior to the close of the comment period.

With respect to past proposed patent licenses, the NIH has asserted two major reasons for declining to provide the information requested by KEI: that the information sought was irrelevant, or that it was confidential.

The questions KEI asked and Dr. Lambertson did not answer are not irrelevant. They relate to how the NIH had applied the criteria at 35 U.S.C. § 209 governing a federal agency's authority to grant an exclusive license. There can be no issue more relevant to a licensing decision than

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<sup>2</sup> <https://www.ott.nih.gov/technology/e-028-2019>.

<sup>3</sup> <http://neoinmunetech.com/company/overview.html>.



how the NCI determined that an exclusive license was a necessary incentive (35 U.S.C. § 209(a)(1)) and how it concluded that the scope of the license is not broader than necessary (35 U.S.C. § 209(a)(2)).

Likewise, the information Dr. Lambertson failed to provide was not confidential business information.

Federal law and regulations regarding government patent licenses do not make all aspects of license applications confidential. Rather, they establish the confidentiality only of a license applicant's commercialization plans and periodic utilization reports—items that KEI did not request.

The Bayh-Dole Act gives the public a role in licensing decisions concerning inventions that are funded and owned by the public. Because the questions KEI asked and Dr. Burke failed to answer were relevant and non-confidential, Dr. Burke had no basis for not answering them and the NIH's lack of transparency undermined our ability to comment on the license.

2. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public's interest in the NIH-funded technology:

1. **Exclusivity.** If the NIH decides to grant exclusive rights to the subject invention, it should limit exclusivity to the European Union, Japan and other high-income countries, but not the United States, so that countries that did not fund the R&D underlying the invention would bear the costs of the exclusivity, while the U.S. residents would not. The NIH should also limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.
1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give

effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”

3. **Global registration and affordability.** The license should require Neolmmune to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the invention exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”
6. **Transparency of R&D outlays.** Neolmmune should be required to file an annual report to the NIH, available to the public, on the R&D costs associated with the development of any product or service that uses the invention, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to

obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

## **Conclusion**

The NIH's failure to answer KEI's questions about this license has undermined our right, as members of the public, to comment on it. Because the license disposes of government-owned property, the NIH may not grant the license unless it first requests the antitrust advice of the U.S. Attorney General. 40 U.S.C. § 559. In the event that the NIH grants the license, we ask that it incorporate the provisions listed above, which are designed to protect the public interest in the licensed technologies and to accomplish the policies outlined in the PHS Technology Transfer Manual.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment



**b5**

---

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/20/2020 10:57:52 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Hi Mark,

KEI is following up with a repeat of two of their questions.

b5

Thanks,

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

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Fax: 240-276-5504

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**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Sunday, April 19, 2020 8:37 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

When did you or anyone at the NIH address how the NIH concluded that exclusivity was necessary for this license, and when did you address how you determined the appropriate scope of the license?

Thank you in advance for your clarification.

Sincerely,  
Kathryn Ardizzone

On Sun, Apr 19, 2020 at 8:25 AM Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> wrote:

REL0000025116

Dear Ms. Ardizzone,

Thank you for your email.

Answers to questions 1 and 2 are provided below in red. Regarding the remaining questions, these have been addressed in past correspondence between NIH and your organization. Please refer to our previous answers.

Regards,

David A. Lambertson, Ph.D.

Senior Technology Transfer Manager

Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)

<http://ttc.nci.nih.gov/>

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Bethesda, MD 20892-9702 (USPS)

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**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Monday, April 13, 2020 1:45 PM

**To:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>

REL0000025116

**Subject:** Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

Please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer."

1. At what stage of research and development is the covered invention? - The invention is considered to be at a preclinical stage of development.
2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers? - The invention is considered to be at a preclinical stage of development, thus no clinical trials are currently underway.
3. Please provide an estimate of how much the NCI has spent to develop the invention.
4. On what basis did the NCI conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?
  - a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?
  - b. Did you estimate the cost of bringing the invention to market?
5. What is the contemplated period of exclusivity for the license?
6. How has the NCI determined that the scope of the license is not broader than necessary?
7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?
8. What royalty rates/payments will the NCI receive for the license?
9. Please provide a list of the firms that applied to license the covered invention.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

REL0000025116

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 11/4/2019 9:59:32 PM  
**To:** Burke, Andy (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305e280edc664e68939d4348603f56e6-burkear]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: CAR licenses?

Thanks Andy!

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Sent:** Monday, November 04, 2019 10:57 AM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: CAR licenses?

Hi Dale,

Your recollection is largely correct. b4,b5  
b4,b5

Regarding b4,b5  
b4,b5

Andy

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Friday, November 1, 2019 4:59 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: CAR licenses?

Ok thanks. The way I remember it is that b4,b5  
b4,b5

Thanks, Dale

REL0000025118

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, November 01, 2019 2:56 PM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: CAR licenses?

b5

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, November 1, 2019 12:07 PM  
**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: CAR licenses?

Ok but what I meant was

b5

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
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**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Sent:** Friday, November 01, 2019 12:02 PM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: CAR licenses?

Hi Dale,

b5

Andy

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, November 1, 2019 11:45 AM  
**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

REL0000025118

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** RE: CAR licenses?

Andy

b5

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
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Bethesda, MD 20892  
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**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Sent:** Wednesday, October 30, 2019 12:26 PM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Fenn, Tedd (NIH/NCI) [E] <[tedd.fenn@nih.gov](mailto:tedd.fenn@nih.gov)>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** RE: CAR licenses?

Hi Dale,

b5

Thank you,

Andy

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Wednesday, October 30, 2019 11:58 AM

**To:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Fenn, Tedd (NIH/NCI) [E] <[tedd.fenn@nih.gov](mailto:tedd.fenn@nih.gov)>; Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** RE: CAR licenses?

Tedd, Andy

b5

b5

Thanks, Dale

**From:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>

**Sent:** Wednesday, October 30, 2019 11:45 AM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** RE: CAR licenses?

REL0000025118



b5

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Wednesday, October 30, 2019 11:43 AM  
**To:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: CAR licenses?

b5

**From:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>  
**Sent:** Wednesday, October 30, 2019 11:41 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: CAR licenses?

b5

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

REL0000025118

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**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Wednesday, October 30, 2019 11:39 AM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Cc:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** CAR licenses?

Dave:

I am trying to write the response to KEI

b5

b5

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Prabhu, Yogikala (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6DC0FA019B424F05B6F86D734D5B894A-PRABHUYO]  
**Sent:** 2/3/2020 4:41:39 PM  
**To:** Rohrbach, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Tung, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=673ea50c713a457f82e4c3ecbf361d03-tungpp]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkeleyd]  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Attachments:** KEI response letter- Teralimmune license-YP -Jan 30.docx; FRN- Teralimmune Exclusive license - 2020-00721.pdf; Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

Dear Mark,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!  
Best Regards,  
Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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**From:** Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>  
**Sent:** Monday, February 3, 2020 11:37 AM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] <yogikala.prabhu@nih.gov>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Tung, Peter (NIH/NIAID) [E] <peter.tung@nih.gov>  
**Subject:** RE: KEI questions - Intent to Grant Notice published in the FRN (2020-00721)

Yogi:

You need to forward this to Mark and copy me.

Thanks, Dale

REL0000025120

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Prabhu, Yogikala (NIH/NIAID) [E] <[yogikala.prabhu@nih.gov](mailto:yogikala.prabhu@nih.gov)>  
**Sent:** Monday, February 03, 2020 11:24 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Tung, Peter (NIH/NIAID) [E] <[peter.tung@nih.gov](mailto:peter.tung@nih.gov)>  
**Subject:** KEI questions - Intent to Grant Notice published in the FRN (2020-00721)  
**Importance:** High

Dear Dale,

We have received questions from KEI regarding the Federal Register Notice 2020-00721, entitled "*Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)*," published on Jan 17, 2020. Please find attached our draft response letter for your review and comments. Also attached is a copy of the intent to grant notice for your reference.

Thank you very much!  
Best Regards,  
Yogi

**Yogikala (Yogi) Prabhu, Ph.D.**  
**Technology Transfer and Patent Specialist**

**Technology Transfer and Intellectual Property Office**  
**National Institute of Allergy and Infectious Diseases/NIH**  
5601 Fishers Lane, Suite 6D37 MSC9804  
Rockville, MD 20852  
Phone: 301-761-7789  
Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov)

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REL0000025120

**b5**

**b5**

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Application Waiver/Supplemental A Research .....	HHS 426 .....	45	1	10	450
Application Waiver/Supplemental B Clinical Care .....	HHS 426 .....	35	1	10	350
Total .....	.....	.....	.....	.....	800

**Terry Clark,**

*Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2020-00717 Filed 1-16-20; 8:45 am]

**BILLING CODE 4150-38-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Early Phase Clinical Trials for Psychosocial Interventions.

*Date:* February 11, 2020.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, [dsommers@mail.nih.gov](mailto:dsommers@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Early Phase Clinical Trials—Pharma/Device.

*Date:* February 20, 2020.

*Time:* 11:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center Building (NSC), 6001

Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, [dsommers@mail.nih.gov](mailto:dsommers@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 13, 2020.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-00688 Filed 1-16-20; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to TeraImmune, Inc. ("TeraImmune") located in Rockville, Maryland.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before February 3, 2020 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Dr. Yogikala Prabhu,

Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804; Telephone: (301) 496-2644; Facsimile: (240) 627-3117; Email: [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

- U.S. Patent 9,481,866—issued November 1, 2016, entitled "Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells" [HHS Reference No. E-279-2011/0-US-02]
- U.S. Divisional Application No.15/284,840—filed October 4, 2016, entitled "Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells". [HHS Reference No. E-279-2011/0-US-03]

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory will be the United States and the field of use will be limited to: "Human cell-based therapeutics for the treatment of Hemophilia A in patients that have inhibitory Factor VIII antibodies."

The technology is directed to a method for producing or growing cell populations that are enriched for stable, highly suppressive regulatory T cells (Tregs). Tregs are critical in regulating immune system processes that maintain tolerance to self-antigens and prevent immune mediated diseases. The method takes a population of cells comprising stable, regulatory T cells and enriched for specific CD markers, cultures these cells in the presence of interleukin-2, an anti-CD3 antibody, an anti-CD28 antibody, and oligodeoxynucleotides of specified length having a phosphorothioate backbone, and yields the expansion of the initial population of regulatory T-cells. The expanded Tregs may then be used for the treatment of immune-mediated diseases.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.

The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this notice will be presumed to contain business confidential information, and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 6, 2020.

**Wade W. Green,**

*Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2020-00721 Filed 1-16-20; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

*Date:* February 10–11, 2020.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5205 MSC 7846, Bethesda, MD 20892, (301) 435-1021, [rovescaa@mail.nih.gov](mailto:rovescaa@mail.nih.gov).

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

*Date:* February 12–13, 2020.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* AC Hotel by Marriott National Harbor, 156 Waterfront Street, National Harbor, MD 20745.

*Contact Person:* Karen Nieves Lugo, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 594-9088, [karen.nieveslugo@nih.gov](mailto:karen.nieveslugo@nih.gov).

*Name of Committee:* Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

*Date:* February 12–13, 2020

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

*Contact Person:* Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301-455-2364, [tatiana.cohen@nih.gov](mailto:tatiana.cohen@nih.gov).

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Biostatistical Methods and Research Design Study Section.

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* San Francisco Marriott Fisherman's Wharf, 1250 Columbus Ave., San Francisco, CA 94133.

*Contact Person:* Chittari V. Shivakumar, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-408-9098, [chittari.shivakumar@nih.gov](mailto:chittari.shivakumar@nih.gov).

*Name of Committee:* Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

*Contact Person:* Kenneth Ryan, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301-435-0229, [kenneth.ryan@nih.hhs.gov](mailto:kenneth.ryan@nih.hhs.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Clinical and Integrative Diabetes and Obesity Study Section.

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW, Washington, DC 20036.

*Contact Person:* Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, 301-435-1044, [chenhui@csr.nih.gov](mailto:chenhui@csr.nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott Metro Center, 775 12th Street NW, Washington, DC 20005.

*Contact Person:* Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, MSC, Bethesda, MD 20892, (301) 451-6319, [rojasr@mail.nih.gov](mailto:rojasr@mail.nih.gov).

*Name of Committee:* Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Catamaran Resort, 3999 Mission Boulevard, San Diego, CA 92109.

*Contact Person:* Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-435-1206, [komissar@mail.nih.gov](mailto:komissar@mail.nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-806-2765, [larkinja@csr.nih.gov](mailto:larkinja@csr.nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

*Date:* February 13–14, 2020.

*Time:* 8:00 a.m. to 6:00 p.m.



---

**From:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**Sent:** 1/28/2020 3:21:41 PM  
**To:** Prabhu, Yogikala (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc0fa019b424f05b6f86d734d5b894a-prabhuyo]  
**Subject:** Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

Dear Dr. Prabhu:

At your earliest convenience, please answer the questions below, which concern the "Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)."

1. At what stage of research and development is the technology?
2. Has the invention been investigated in any clinical trials? If so, what are their NCT numbers?
3. How much funding has the government contributed to the development of the technology? What NIH Grant Nos. are associated with it?
4. What is the proposed duration of the license?
5. What analysis was performed in determining that an exclusive license was a necessary incentive and otherwise satisfies 35 U.S.C. 209?
6. How will the NIH ensure that the scope of the license is not broader than reasonably necessary?
7. Please provide a list of firms that applied for this license. Please note that KEI is only seeking the name of any license applicants, and not any confidential material within the license applications.
8. How was Teralmmune selected as the prospective licensee over any other bidders? Did the NIH consider the company's relationship with Yong Chan Kim, the former NIH scientist who invented the technology?

Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/19/2020 12:26:15 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

As requested, below is the response I sent.

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**From:** Lambertson, David (NIH/NCI) [E]  
**Sent:** Sunday, April 19, 2020 8:25 AM  
**To:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Subject:** RE: Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Ms. Ardizzone,

Thank you for your email.

Answers to questions 1 and 2 are provided below in red. Regarding the remaining questions, these have been addressed in past correspondence between NIH and your organization. Please refer to our previous answers.

Regards,

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)

REL0000025121

Rockville, MD 20850-9702 (Overnight/express mail)  
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Fax: 240-276-5504

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**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, April 13, 2020 1:45 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Subject:** Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

Please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer."

1. At what stage of research and development is the covered invention? - The invention is considered to be at a preclinical stage of development.
2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers? - The invention is considered to be at a preclinical stage of development, thus no clinical trials are currently underway.
3. Please provide an estimate of how much the NCI has spent to develop the invention.
4. On what basis did the NCI conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?
  - a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?
  - b. Did you estimate the cost of bringing the invention to market?
5. What is the contemplated period of exclusivity for the license?
6. How has the NCI determined that the scope of the license is not broader than necessary?
7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?
8. What royalty rates/payments will the NCI receive for the license?
9. Please provide a list of the firms that applied to license the covered invention.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500

REL0000025121

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

---

**From:** Wong, Jennifer A (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6603ED16C184B8B83F02F5FA40A05DF-WONGJA]  
**Sent:** 9/26/2019 12:03:29 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Predescu, Alina (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a60e98376e746c7a37640bd40f45149-predescuad]  
**Subject:** RE: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Thanks for sending this. I'd be interested in the response to the Sept 19 letter...once again, strictly for learning purposes.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, September 25, 2019 2:17 PM  
**To:** Wong, Jennifer A (NIH/OD) [E] <wongja@od.nih.gov>; Predescu, Alina (NIH/NCATS) [E] <alina.predescu@nih.gov>  
**Subject:** RE: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

I think they are talking about FDA regulatory exclusivity for IND data.  
The requests are not formal. Given the current situation, I have asked that all proposed responses to comments to intramural proposed exclusive license notices (in the Fed Reg as required by law/reg) be sent to me for review and coordination. As needed, I will seek OGC input. There are long-standing processes within ICs to address any objections that are submitted as a competing license application.

**From:** Wong, Jennifer A (NIH/OD) [E] <wongja@od.nih.gov>  
**Sent:** Wednesday, September 25, 2019 1:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Predescu, Alina (NIH/NCATS) [E] <alina.predescu@nih.gov>  
**Subject:** RE: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Hi Mark. Thank you for sending this.

On page 2, Bullet point 1 they referenced test data protection as a non-patent incentive. I'm unfamiliar with this, can you help me understand it in this context?

They also reference an e-mail from KEI dated August 23, 2019 and a September 5, 2019 response letter. Would you be able to share these with us for learning purposes?

Also, the next time we're all together, could you go over the process for how requests come to TTIP and how responses are vetted and communicated back?

Jennifer

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 24, 2019 4:35 PM  
**To:** Predescu, Alina (NIH/NCATS) [E] <alina.predescu@nih.gov>; Wong, Jennifer A (NIH/OD) [E] <wongja@od.nih.gov>  
**Subject:** FW: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

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**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/16/2020 5:59:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Good afternoon Mark,

Here is my proposed response to Ms. Ardizzone, based on my understanding of how we are treating these inquiries. Please let me know if the response is acceptable, or if there are adjustments I should make before sending it.

Thanks,  
Dave

-----  
Dear Ms. Ardizzone,

Thank you for your email.

Answers to questions 1 and 2 are provided below in red. Regarding the remaining questions, these have been addressed in past correspondence between my office and your organization. Please refer to our previous answers.

Regards,

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

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Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
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Fax: 240-276-5504

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**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, April 13, 2020 1:45 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Subject:** Questions, Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

REL0000025125



Dear Dr. Lambertson:

Please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer."

1. At what stage of research and development is the covered invention?- The invention is considered to be at a preclinical stage of development.  
-
2. Is the invention being investigated in any clinical trials? If so, can you please provide their numbers?- The invention is considered to be at a preclinical stage of development, thus no clinical trials are currently underway.
3. Please provide an estimate of how much the NCI has spent to develop the invention.
4. On what basis did the NCI conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?
  - a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?
  - b. Did you estimate the cost of bringing the invention to market?
5. What is the contemplated period of exclusivity for the license?
6. How has the NCI determined that the scope of the license is not broader than necessary?
7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?
8. What royalty rates/payments will the NCI receive for the license?
9. Please provide a list of the firms that applied to license the covered invention.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 9/24/2019 7:25:52 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, September 24, 2019 3:00 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>  
**Subject:** FW: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Suggestions? b5

**From:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Sent:** Tuesday, September 24, 2019 2:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Hi Mark,

I have no idea how to respond to this... b5

b5

Please also note that b5

Happy to chat further.  
Jim

**From:** kathryn ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Tuesday, September 24, 2019 12:57 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>

REL0000025127



**Subject:** Re: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Dear Jim,

Thank you for bringing this to our attention. I apologize for the unintentional omission of the attachment. Please find our comments, attached here.

Thank you in advance for processing our comments.

Sincerely,  
Kathryn Ardizzone

On Tue, Sep 24, 2019 at 12:45 PM Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov> wrote:

Kathryn,

Thank you for your email, and for James' follow up with the timeline.

Please note that there was nothing attached to your email.

Many thanks,

Jim

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Thursday, September 19, 2019 1:12 PM

**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>

**Cc:** James Love <james.love@keionline.org>; manon.ress@cancerunion.org; Alex Lawson <alawson@socialsecurityworks.org>; Baker, Brook <b.baker@northeastern.edu>

**Subject:** Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Dear Dr. Knabb:

Attached, please find the comments of KEI, UACT, SSW, HealthGAP, and Brook Baker concerning the proposed exclusive NIH patent license to Lyell Immunopharma, as referenced in the Federal Register notice located at 84 FR 43148, "Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies."

REL0000025127

Thank you in advance for your consideration of these comments. We look forward to receiving the NIH's response.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 4/13/2020 9:02:35 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** FW: Questions, Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy

Hi Mark,

Answers to KEI's questions are provided for your review. Please see my question regarding KEI's question #9.

Thank you,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, April 13, 2020 1:42 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** James Love <james.love@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>  
**Subject:** Questions, Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy

Dear Dr. Burke:

Please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy."

1. At what stage of research and development are the covered inventions?

b5

2. Are any of the inventions being investigated in any clinical trials? If so, can you please provide their numbers?

b5

3. Please estimate how much the NCI has spent to develop the inventions.

b5

4. On what basis did the NCI conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?

b5

a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?

b. Did you estimate the cost of bringing the technologies to market?

5. What is the contemplated period of exclusivity for the license?

b5

6. How has the NCI determined that the scope of the license is not broader than necessary?

b5

7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?

8. What royalty rates/payments will the NCI receive for the license?

b5

9. Please provide a list of the firms that applied to license each of the covered inventions.

b5

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

**From:** Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]  
**Sent:** 9/24/2019 6:40:19 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)  
**Attachments:** KEI, UACT, SSW, HealthGAP, Baker to NIH re\_ Lyell Immunopharma License.pdf

Hi Mark,

I have no idea how to respond to this...

b5

b5

Please also note that

b5

b5

Happy to chat further.

Jim

**From:** kathryn ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Tuesday, September 24, 2019 12:57 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>  
**Subject:** Re: Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Dear Jim,

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Thank you in advance for processing our comments.

Sincerely,  
Kathryn Ardizzone

On Tue, Sep 24, 2019 at 12:45 PM Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov> wrote:

Kathryn,

Thank you for your email, and for James' follow up with the timeline.

REL0000025131

Please note that there was nothing attached to your email.

Many thanks,

Jim

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Thursday, September 19, 2019 1:12 PM

**To:** Knabb, Jim (NIH/NCI) [E] <[jim.knabb@nih.gov](mailto:jim.knabb@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; manon.ress@cancerunion.org; Alex Lawson <[alawson@socialsecurityworks.org](mailto:alawson@socialsecurityworks.org)>; Baker, Brook <[b.baker@northeastern.edu](mailto:b.baker@northeastern.edu)>

**Subject:** Comments of KEI, UACT, SSW, HealthGAP and Brook Baker on Proposed Exclusive License to Lyell Immunopharma (84 FR 43148)

Dear Dr. Knabb:

Attached, please find the comments of KEI, UACT, SSW, HealthGAP, and Brook Baker concerning the proposed exclusive NIH patent license to Lyell Immunopharma, as referenced in the Federal Register notice located at 84 FR 43148, "Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies."

Thank you in advance for your consideration of these comments. We look forward to receiving the NIH's response.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

REL0000025131

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September 19, 2019

Jim Knabb, Ph.D.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive  
Bethesda, MD 20892-9702  
Via email to [jim.knabb@nih.gov](mailto:jim.knabb@nih.gov)

**Re: “Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies,” 84 FR 43148**

Dear Dr. Knabb:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Social Security Works (SSW), Health GAP, and Brook Baker offer the following comments on the National Institutes of Health (NIH)’s prospective grant of an exclusive, worldwide license in “CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies” to Lyell Immunopharma, Inc., as noticed at 84 FR 43148.

CAR therapies, which treat advanced-stage cancers for which other treatment options have failed, have been introduced on the market at extremely high prices, restricting reimbursements, creating fiscal toxicity for patients, and raising premiums and taxes.

Any license the NIH negotiates must comply with the criteria set forth at 35 U.S.C. § 209, which, among other restrictions, allows a federal agency to license a government-owned technology on an exclusive basis only when “granting the license is a reasonable and necessary incentive to . . . call forth the investment capital and expenditures needed to bring the invention to practical application[.]” and the “scope of exclusivity” is “not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” 35 U.S.C. § 209(a)(1)-(2).

The NIH is either conducting or sponsoring at least two Phase 1 clinical trials associated with the technology, making it a less-costly, more attractive investment for potential licensees and reducing the need for broad, exclusive rights in this cancer treatment.



We have several objections to the process, question the timeliness of the license, and object to licensing the patents without safeguards on pricing and access.

1. The information provided by the NIH is not sufficient to demonstrate that it properly analyzed whether an exclusive license is “a reasonable and necessary incentive” under 35 U.S.C. § 209(a)(1), for example, by considering the non-patent incentives that exist regarding the Orphan Drug Act, the Priority Review Voucher and test data protection, in the context of a treatment already in two clinical trials;
2. The NIH has not demonstrated that it properly analyzed whether the scope of the license is no broader than necessary to induce the investment needed to bring the technology to market under 35 U.S.C. § 209(a)(2), including, in particular, the number of years of exclusivity – the most important and manageable limitation on the scope of the monopoly rights;
3. The NIH was not fully transparent about the license and reached a final determination before considering all timely-submitted public comment, in conflict with 35 U.S.C. § 209(e). Among the facts not disclosed was the NIH costs associated with financing the invention, including in particular the costs associated with financing two clinical trials, one of which is taking place on the NIH campus; and
4. The NIH apparently has not sought the advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

In the event that the NIH grants the license over our objections, we request that the license agreement incorporates a series of provisions designed to safeguard the public interest and ensure that the license implements the policy objectives of the Bayh-Dole Act and Public Health Service (PHS) Technology Transfer Policy Manual.

## **Background**

### *The Inventions*

The Federal Register notice describing the license, located at 84 FR 43148, lists two NIH-owned inventions: “E-016-2015: Chimeric Antigen Receptor Targeting both CD19 and CD22” and “E-017-2017: CD19/CD22 Bicistronic CAR Targeting Human B-Cell Malignancies.”

The inventions have potential indications in “hematological cancers such as chronic lymphocytic leukemia (CLL), hairy cell leukemia (HCL) acute lymphoblastic leukemia (ALL) and lymphoma”<sup>1</sup> and “pediatric, blood-derived cancers.”<sup>2</sup>

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<sup>1</sup> <https://www.ott.nih.gov/technology/e-106-2015-0>.

<sup>2</sup> <https://www.ott.nih.gov/technology/e-106-2015-0> and <https://www.ott.nih.gov/technology/e-017-2017>.

The federal register notice lists the following intellectual property rights as being associated with the inventions:

- U.S. Provisional Patent Application 62/135,442, filed March 19, 2015 (E-106-2015-0-US-01);
- International Patent Application PCT/US2016/023055, filed March 18, 2016 (E-106-2015/0-PCT-02);
- U.S. Patent Application No.: 15/559,485, filed September 19, 2017 (E-106-2015/0-US-03);
- U.S. Provisional Patent Application 62/506,268, filed May 15, 2017 (E-017-2017-0-US-01); and
- International Patent Application PCT/US2018/032,809, filed May 15, 2018 (E-017-2017/0-PCT-02).

Of the above listed patent applications, only PCT/US2016/023055 and 15/559,485 were accessible on public databases.

The licensed technology may offer cancer patients better treatment outcomes than existing CAR therapies. According to U.S. Patent Application No.:15/559/485, “[t]he inventive dual specific CARs may provide many advantages [over existing CAR therapies, which target only the CD19 antigen]”, including “greater potency as compared to a CAR that has antigenic specificity for only one of CD19 and CD22 (but not both)” and the ability to “reduce or prevent cancer cell escape due to loss of expression of one of CD19 or CD22 by the cancer cell.”

#### The Prospective Licensee

The prospective licensee, Lyell Immunopharma, Inc. (“Lyell”), is a relatively new biotech company, incorporated in Delaware on June 29, 2018. It is registered to conduct business in California, where it is headquartered.

Lyell’s website, [www.lyell.com](http://www.lyell.com), lists the company’s “Senior Team” and Board of Directors, but provides little other information about the company. Items such as “Press Releases,” “Publications,” and “News” link to webpages stating “[c]heck back later for updates.”

Lyell’s CEO, Rick Klausner, was the director of the NCI until 2001 and since has been involved in a larger number of venture capital and biomedical firms, including companies like Juno Therapeutics that have benefited enormously from licenses in NIH-funded inventions and two NIH CRADAs, to mention one example.

## Argument

### 1. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license.

Section 209 of the Bayh-Dole Act authorizes a federal agency to grant an exclusive license in government-owned technology only if “granting the license is a reasonable and necessary incentive to . . . (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public[.]” 35 U.S.C. § 209(a)(1).

It is our understanding that the NIH has not undertaken a serious evaluation of the adequacy of existing incentives and subsidies, relating to practical application of the inventions, in order to evaluate whether or not an exclusive license was a “reasonable and necessary incentive.”

On August 23, 2019, KEI emailed you a list of questions about the license, including the following question:

3. What is the NIH’s rationale for concluding that an exclusive, rather than a non-exclusive, or a partially-exclusive license is a necessary incentive under 35 U.S.C. § 209?
  - a. Did the NIH estimate the amount of investment required to bring the technology to practical application?
  - b. Did the NIH consider the incentives from the Orphan Drug Act regulatory exclusivity for rare diseases or FDA rules on exclusive rights to rely on regulatory test data as inadequate to protect the private investment in the technology?

Rather than answering this, or the majority of KEI’s questions, on September 5, 2019, you emailed KEI a letter that reads as a final determination regarding the proposed license (and, in fact, borrows language from many of the NIH’s previous decision letters). The letter states, in pertinent part:

Thank you for providing us with your comments regarding the aforementioned Federal Register notice.

. . .

[W]e determined that the criteria set forth in 37 C.F.R. 404.7(a)(1)(ii-iii) have been satisfied. Lyell demonstrated the scientific and financial capacity to develop CAR-T therapeutics to treat B cell malignancies. The scope of the license proposed is necessary for incentivizing the company to undertake the development risks to develop this type of therapy. The grant of exclusivity to the Government-owned intellectual property seeks to fulfill the government’s interest in promoting the public health and public access to therapeutics.

In addition to the procedural issues with the letter, this explanation misses the point. While it is appropriate for the NIH to consider a prospective licensee's capacity to develop the technology, the statutory standard requires the NIH to determine if an exclusive license "a reasonable and necessary incentive" for achieving practical application of the invention.

To answer that question, the NIH must consider information *beyond* the financial capabilities of the prospective licensee. Merely stating that worldwide and life-of-patent exclusivity, with no strings attached on pricing, is a positive for the investors, is not enough.

There are at least six factors that should be considered when determining the necessary incentive under 35 U.S.C. § 209:

1. The costs of financing research and development and bringing the invention to market, including clinical trial costs (and the extent to which those costs may be covered by the Orphan Drug Tax Credit, Research Credit, or reimbursement by health insurance or other subsidies, as well as any expected additional subsidies from governments or charities, including, for example, additional grants or continued or new collaborations with the NIH or other government agencies);
2. The government's investment in R&D and the development stage of the technology;
3. The existence of non-patent incentives, including, for example, test data protection, Orphan Drug exclusivity and the award of one or more priority review vouchers;
4. The existence of patent exclusivity from other, non-NIH owned patents, that may be used to block entry by competitors for some but not necessarily all uses of the patents (noting that Zolgensma required licensing from four separate patent estates);
5. The anticipated cost to manufacture the resultant invention; and
6. The expected post-market entry profitability of the invention, by year.

Consider, for example, a new CAR treatment that is expected to generate \$400 million per year (Yescarta generated \$99 million in the 2nd quarter of 2019), where the costs of trials are expected to be less than \$30 million (200 patients at \$150,000 per patient), before reductions for tax credits, insurance reimbursements or other subsidies.

Even if the risks associated with the investments in clinical trials are daunting, the risk-adjusted costs of the trials would be less than the revenue from a single year of operation. If the net margin for sales in a year were 50 percent, the project would be a good investment even if exclusivity was limited to five years, the same term that the Bayh-Dole Act permitted for federally-funded patents held by non-government patent holders when the Act was passed. And, this does not even consider the benefits of a possible priority review voucher.

Given the research and development status of the licensed inventions, we estimate that the costs and risks associated with bringing this technology to market are relatively low compared to other licensing opportunities in earlier-stage inventions.

In an email dated September 6, 2019, you stated that the following trials appear to be associated with the licensed technology:

**NCT03448393**

Title: "CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults With Recurrent or Refractory CD19/CD22-expressing B Cell Malignancies"

Actual Study Start Date: 3/26/2018

Estimated Primary Completion Date: 12/1/2021

Phase: 1

Patient Enrollment: 89

NIH Grant: None listed

Principal Investigator: Nirali N Shah,  
NCI

**NCT03241940**

Title: "Phase I CD19/CD22 Chimeric Antigen Receptor T Cells in Peds Recurrent/Refractory B Cell Malignancies"

Actual Study Start Date: 10/20/2017

Estimated Primary Completion Date: 8/1/2025

Phase: 1

Patient Enrollment: 50

NIH Grant: P30CA124435

Principal Investigator: Crystal Mackall,  
Stanford University.

Both trials are Phase 1. The NIH will have paid for the riskiest stage of clinical trial testing in the FDA approval process.

The first trial listed, NCT03448393, is being conducted by the NCI at its laboratories in Bethesda, Maryland. The second is funded by NIH Grant No. P30CA124435.

The fact that the government is funding two clinical trials, including one conducted on the NIH campus by NCI employees, indicates that these inventions have a higher likelihood of success than other technologies licensed at earlier phases of development.

We also note that the first two CAR T approvals, for Yescarta and Kymriah, were granted orphan drug status under the Orphan Drug Act of 1983, 21 U.S.C. §§ 360aa–360ee. The subsidies associated with Orphan Drug designation, including a 25% tax credit on clinical trials, must be taken into account when analyzing any likely additional R&D costs a licensee would incur in commercializing the licensed technology.

*Other Incentives*

The licensed inventions likely would qualify for additional, valuable government incentives.

Yescarta and Kymriah qualified for seven years of Orphan Drug exclusivity for certain indications, as well as 12 year of test data protection on all indications. In the European Union, those protections are 10 and 11 years, respectively. Similar protections exist in Japan, Canada, and in many other countries.

The FDA granted Novartis a priority review voucher for Kymriah.<sup>3</sup> The subject technology has indications in pediatric populations and rare diseases and thus will likely receive a priority review voucher as well. In April 2018, Spark Therapeutics sold a priority review voucher for \$110 million.<sup>4</sup>

In determining whether exclusivity is a “reasonable and necessary incentive,” the NIH must take into consideration the likelihood that the new technologies will receive Orphan Drug market exclusivities and/or priority review vouchers, and evaluate the incentive that the 12 years of test data provides, even in the absence of an exclusive patent license.

2. The NIH has not demonstrated that it properly analyzed whether the scope of rights in this license will not be greater than reasonably necessary to induce the investment needed to commercialize the inventions.

Under Section 209 of the Bayh Dole Act, executing an exclusive license in government-owned inventions is not a binary decision: grant or do not grant a fully-exclusive, worldwide, life-of-patent license. Rather, under 35 U.S.C. § 209(a)(2), the scope of an exclusive license must “not [be] greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]”

A federal agency proposing to grant an exclusive license must determine the following terms related to the scope of the license:

- The period of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (i.e., five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (i.e., targeted diseases).

The NIH has not demonstrated that it makes any effort to determine the number of years of exclusivity that are reasonably necessary to achieve regulatory approval and commercialization.

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<sup>3</sup>

<https://www.federalregister.gov/documents/2017/09/11/2017-19130/issuance-of-priority-review-voucher-rare-pediatric-disease-product>

<sup>4</sup>

<http://ir.sparktx.com/news-releases/news-release-details/spark-therapeutics-sells-priority-review-voucher-110-million>

In KEI's August 23, 2019 email, KEI asked you about the duration of exclusivity for the proposed license, and whether "the NIH [has] undertaken an economic analysis to determine if a shorter exclusivity period such as a five or 10 year term would be a sufficient incentive under 35 U.S.C. 209 for the licensed technologies[.]"

You did not answer. Rather, you stated: "Many of your questions relate to terms in the license which have not yet been negotiated and would be business confidential."

There is an inherent contradiction between the idea that the terms of the license have yet to be determined and your statements, in the preceding paragraph, that "[NIH] ha[s] determined that the criteria set forth in 37 C.F.R. 404.7(a)(1)(ii)-(iii) have been satisfied[.]" and that "[t]he scope of the license proposed is necessary for incentivizing the company to undertake the developmental risks to develop this type of therapy."

Setting aside the fact that the NIH apparently rendered a decision about the license before considering all timely-submitted public comments, it is impossible for the NIH to find that the scope of the license satisfies Section 209 and the associated federal regulations if the NIH has not yet considered what the scope will be.

Based on this, and prior interactions between KEI and the NIH, it appears that the NIH never negotiates an exclusive license for a period shorter than life-of-patent. Such a policy or practice would violate Section 209, which requires that federal agencies negotiate exclusive licenses on a case-by-case basis, and mandates that the scope of a license in federally-owned inventions is no greater than reasonably necessary.

3. The NIH was not fully transparent about the license and reached a final determination before considering all timely-submitted public comment, in conflict with 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely-submitted comments. 35 U.S.C. § 209(e).

As noted previously, on August 23, 2019, KEI emailed you a list of questions related to the criteria for granting an exclusive license, such as the stage of research and development of the invention, whether any clinical trials were associated with the technology, the duration of the license, and whether NIH sought the advice of the Attorney General.

On September 5, 2019, you emailed KEI a response letter that not only failed to answer many of KEI's questions, but also stated that the NIH had determined that the relevant criteria are satisfied by the license. The deadline to submit comments was two weeks away.

Reaching a conclusion about a license before considering all timely-submitted comments conflicts with 35 U.S.C. § 209(e), which states that “[n]o exclusive or partially exclusive license may be granted . . . unless . . . the Federal agency has considered all comments received before the end of the comment period[.]” Because the comment period had not yet closed, and KEI had not, in fact, submitted its comments, it was premature for the NIH to conclude that the proposed exclusive license to Lyell satisfied the relevant criteria.

After KEI pointed out that the August 23, 2019 email was a set of questions, and not comments or suggestions, the NIH never followed up with answers to many of the questions asked (other than to provide the clinical trial numbers associated with the invention). For the public to meaningfully comment on a license, it must have basic information from the NIH.

One issue, in particular, about which the NIH was not transparent was trial costs. You stated in your letter that you “do not have additional information related to the costs, etc. of these clinical trials.” While it may be the case that you do not personally have such information, someone within NIH should be able to disclose such data.

In regard to extramural research specifically, as part of the NIH grant process, grant recipients are required to submit a variety of reports and forms, many of which involves disclosures of anticipated or actual expenditures. For example, according to the NIH website, “[r]ecipients of federal funds are required to report the status of funds for grants or assistance agreements to the sponsor of the grant[.]” which involves “submit[ting] a statement of expenditures associated with the grant to the sponsor[.]” using an SF 425 form.<sup>5</sup> The NIH’s recordkeeping procedures demonstrates that it keeps track of trial costs.

4. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. 559.

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license would not be anticompetitive.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property.” The statute exempts personal property if the fair market value is less than \$3,000,000, but specifically excludes “a patent, process, technique, or invention” from that exception.

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<sup>5</sup> [https://era.nih.gov/erahelp/Commons/FFR/ffr\\_intro.htm](https://era.nih.gov/erahelp/Commons/FFR/ffr_intro.htm).



The regulation 41 C.F.R. § 102-75.270 also makes clear the inclusion of patents “irrespective of cost.”

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked you whether the NIH requested the advice of the U.S. Attorney General concerning the licenses. You did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

“The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.”

We disagree.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants an exclusive license in a federally-owned invention, it is disposing of a government property interest so as to trigger 40 U.S.C. § 559.

5. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the licenses implement the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public's interest in the NIH-funded technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."
3. **Global registration and affordability.** The license should require Intima Bioscience to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of

exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

## Conclusion

We object to the prospective license for the reasons stated herein. If the NIH decides to execute the license over our objections, we request that, at the very least, it includes the safeguards we have proposed, which are designed to implement the Bayh-Dole Act's stated policy objective that government-sponsored inventions are available to the public on reasonable terms, as well as the PHS Technology Transfer Manual's policy of promoting access in developing countries.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment  
Social Security Works  
Health GAP  
Brook Baker

---

**From:** Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]  
**Sent:** 1/9/2020 8:15:24 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Plank-Bazinet, Jennifer (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a7faf0b33bb4b90b07b212e49ec08e3-plankji\_f24]; Creery, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6ed3522d2c40dab248a553dad50e7b-creeryjd]  
**Subject:** RE: Could you please send me the old BRAIN brief on drug pricing?  
**Attachments:** Exported BRAIN Record (Drug Pricing).docx; Exported BRAIN Record (Drug Pricing)

Hi Mark,

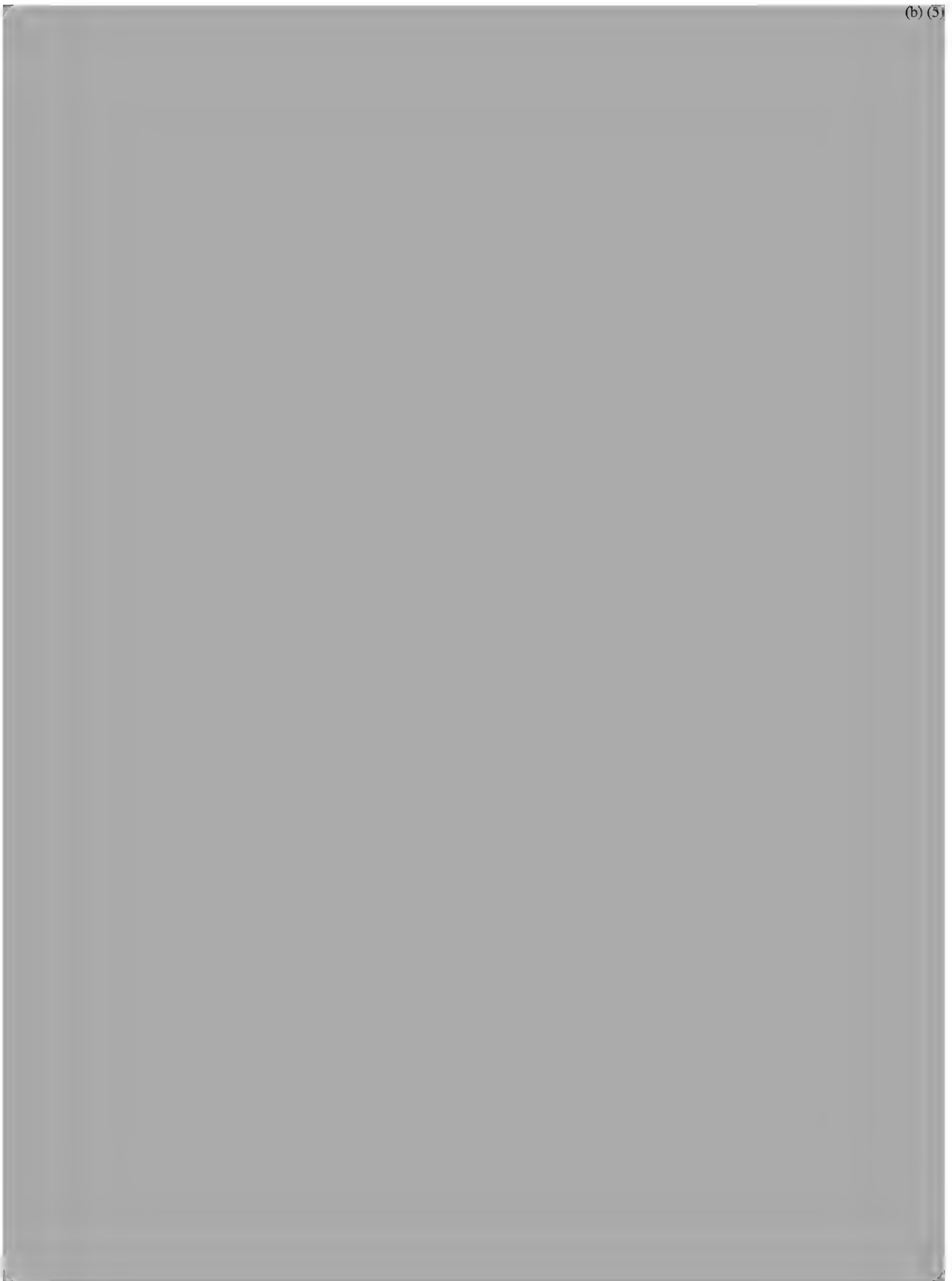
Last year's Drug Pricing BRAIN record is attached. Happy to help you get into BRAIN this afternoon!

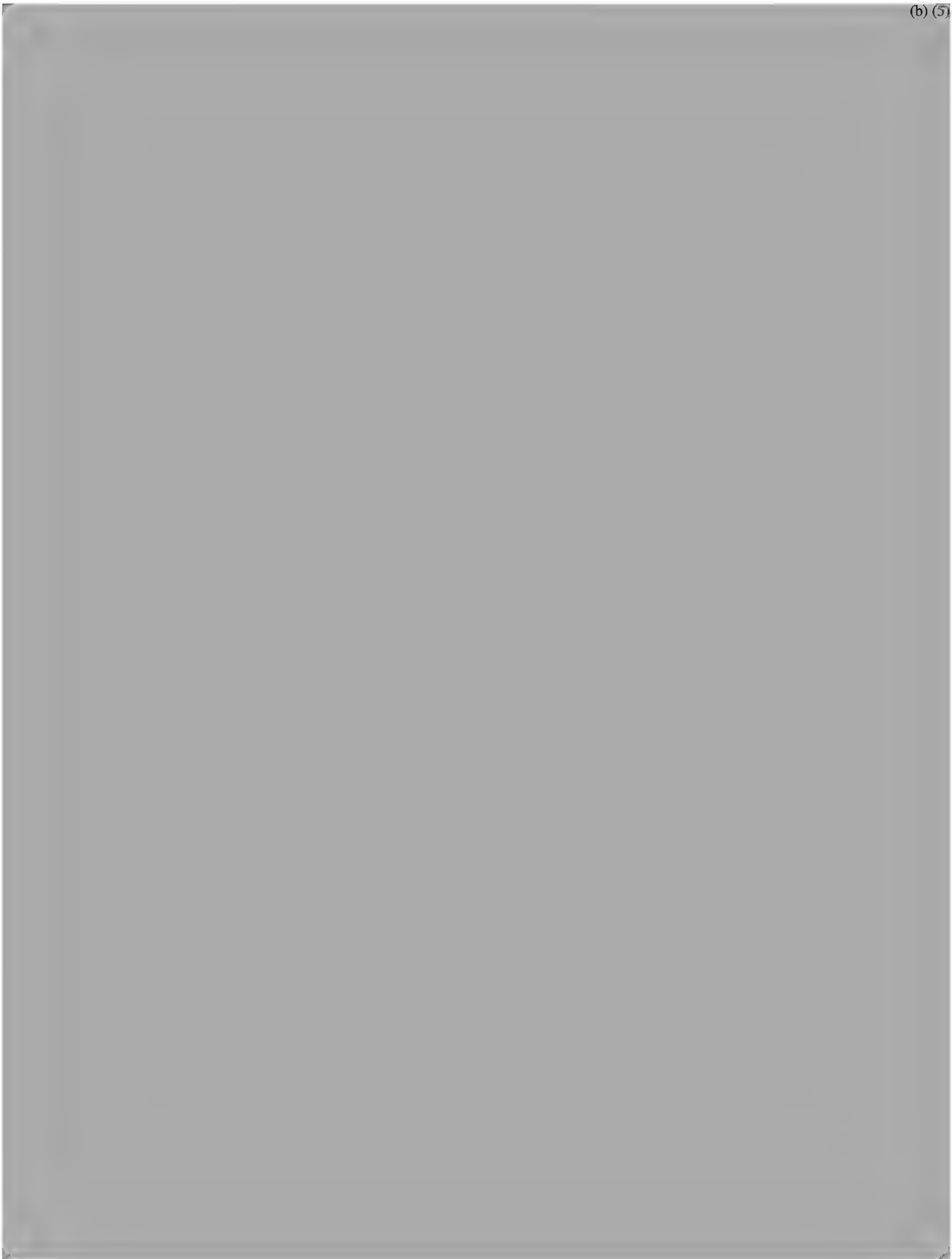
Best,  
Ursula

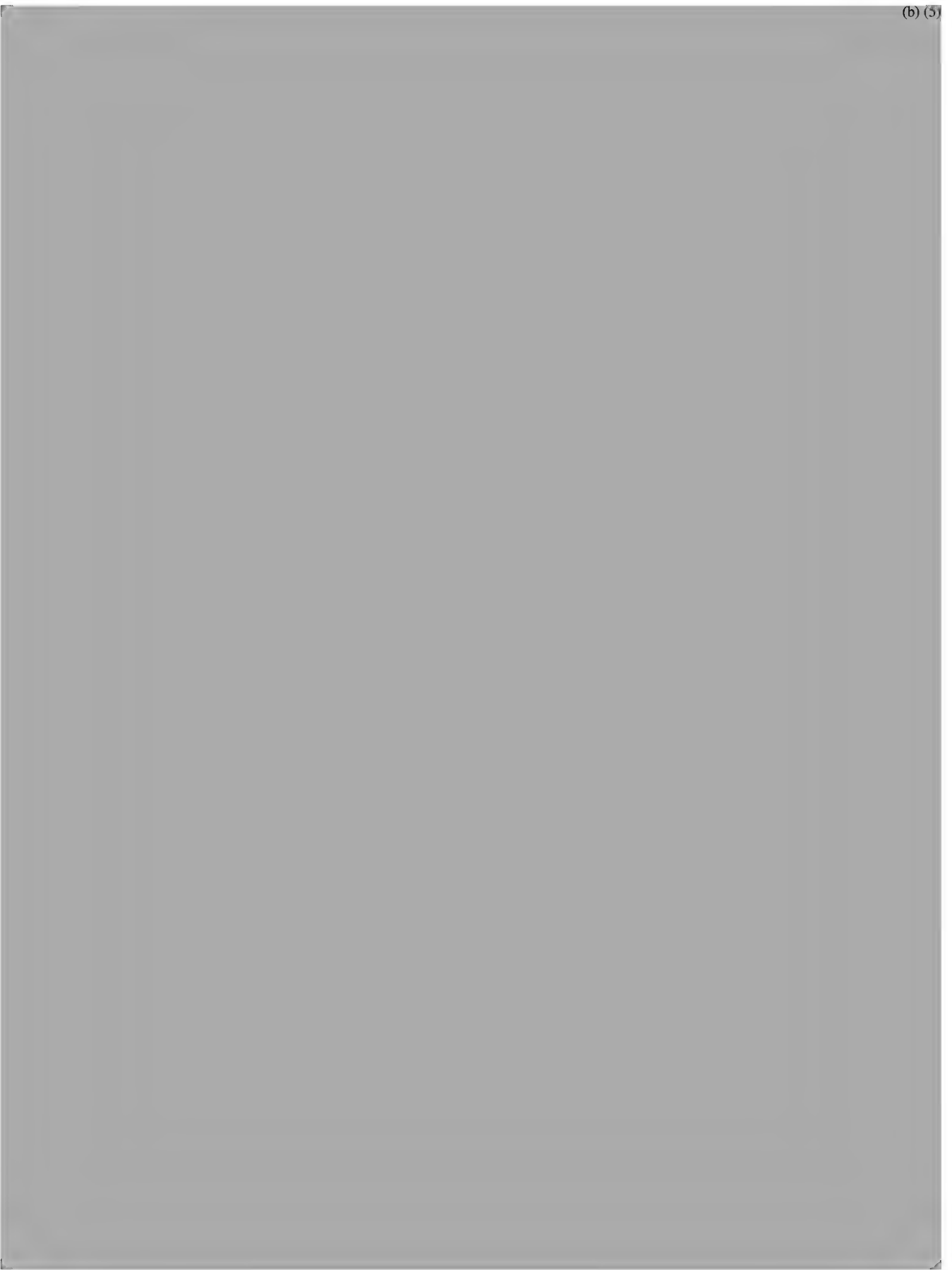
**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Thursday, January 9, 2020 2:56 PM  
**To:** Plank-Bazinet, Jennifer (NIH/OD) [E] <[jennifer.bazinet@nih.gov](mailto:jennifer.bazinet@nih.gov)>  
**Subject:** Could you please send me the old BRAIN brief on drug pricing?

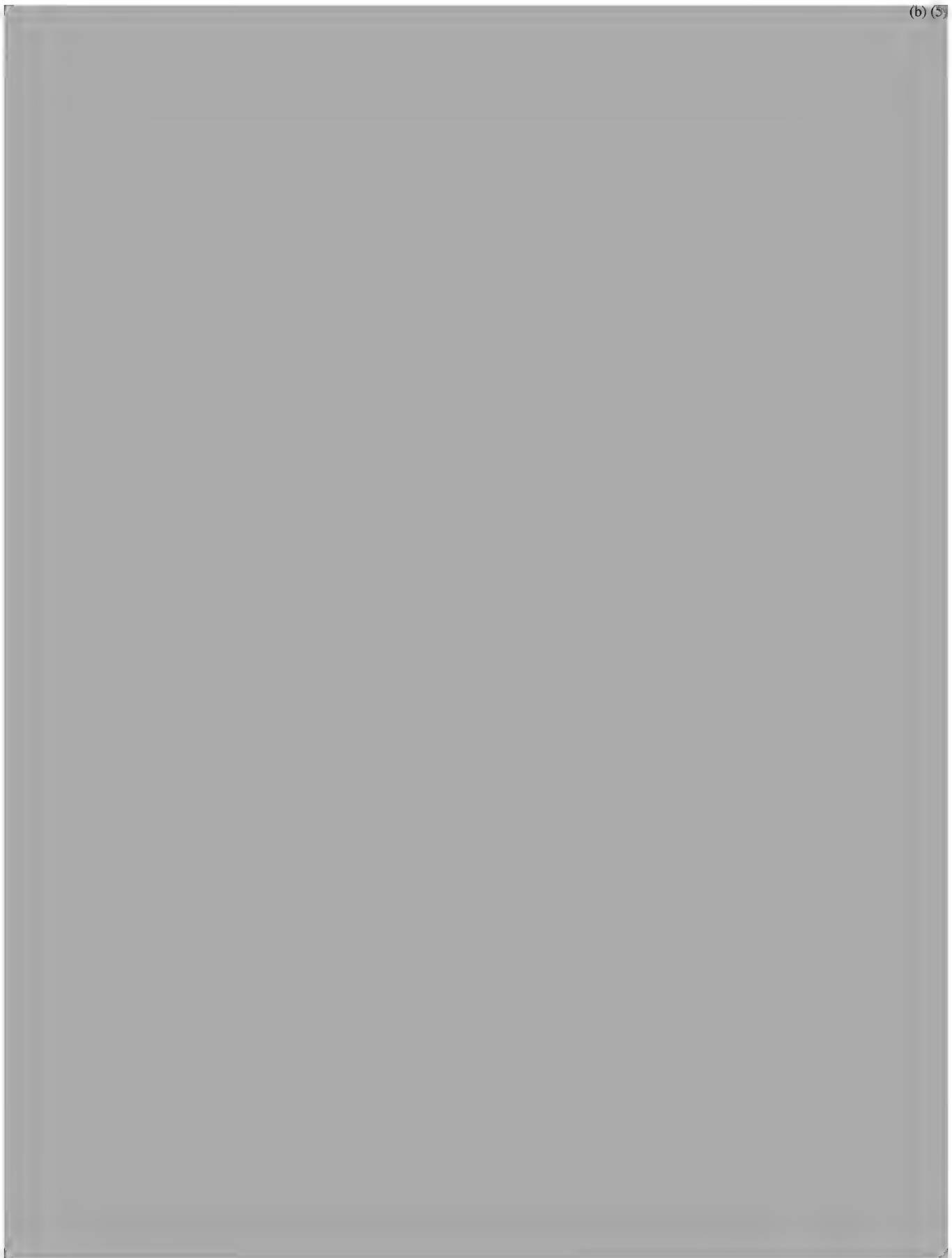
I can't get into BRAIN. Thanks

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health

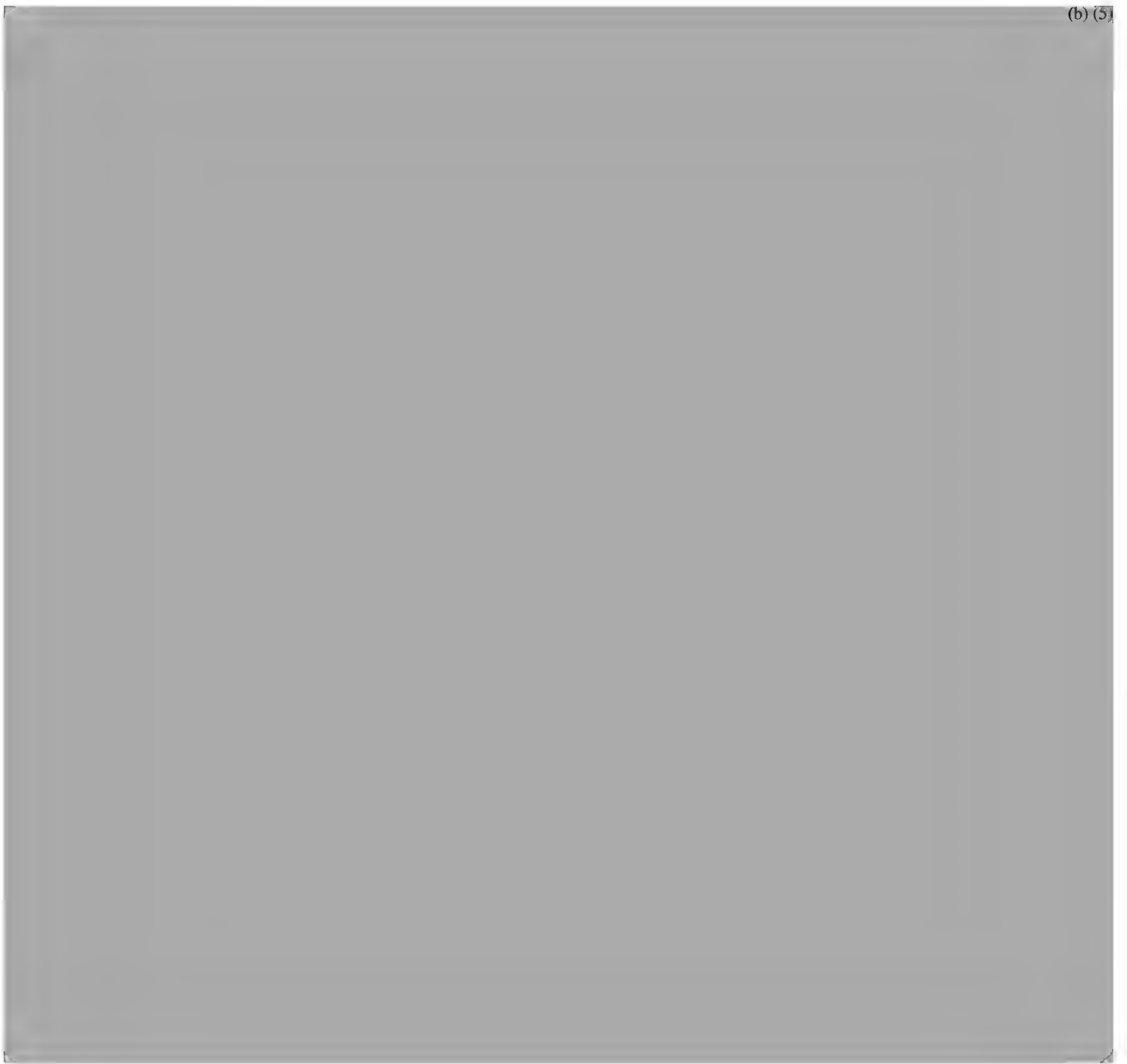






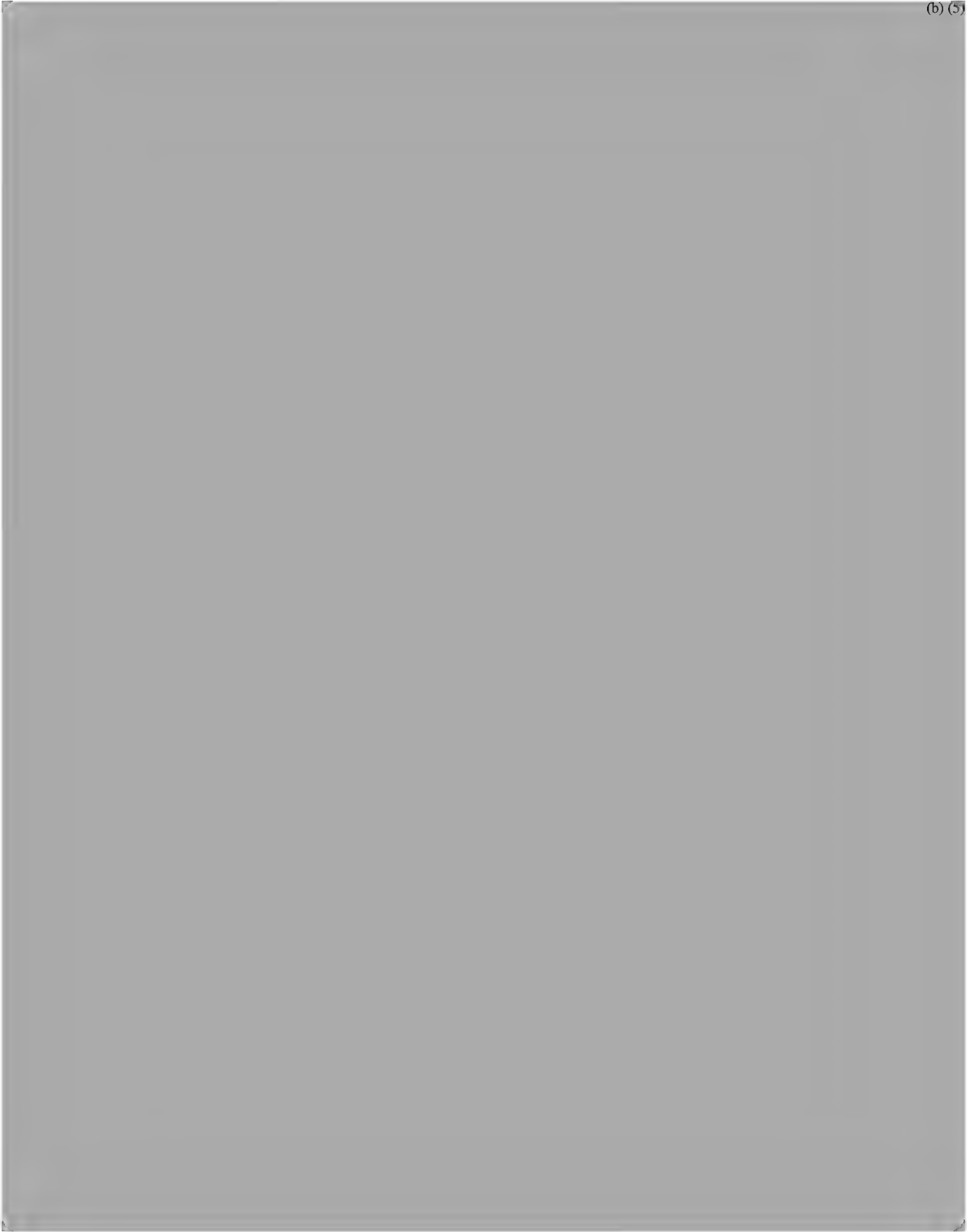


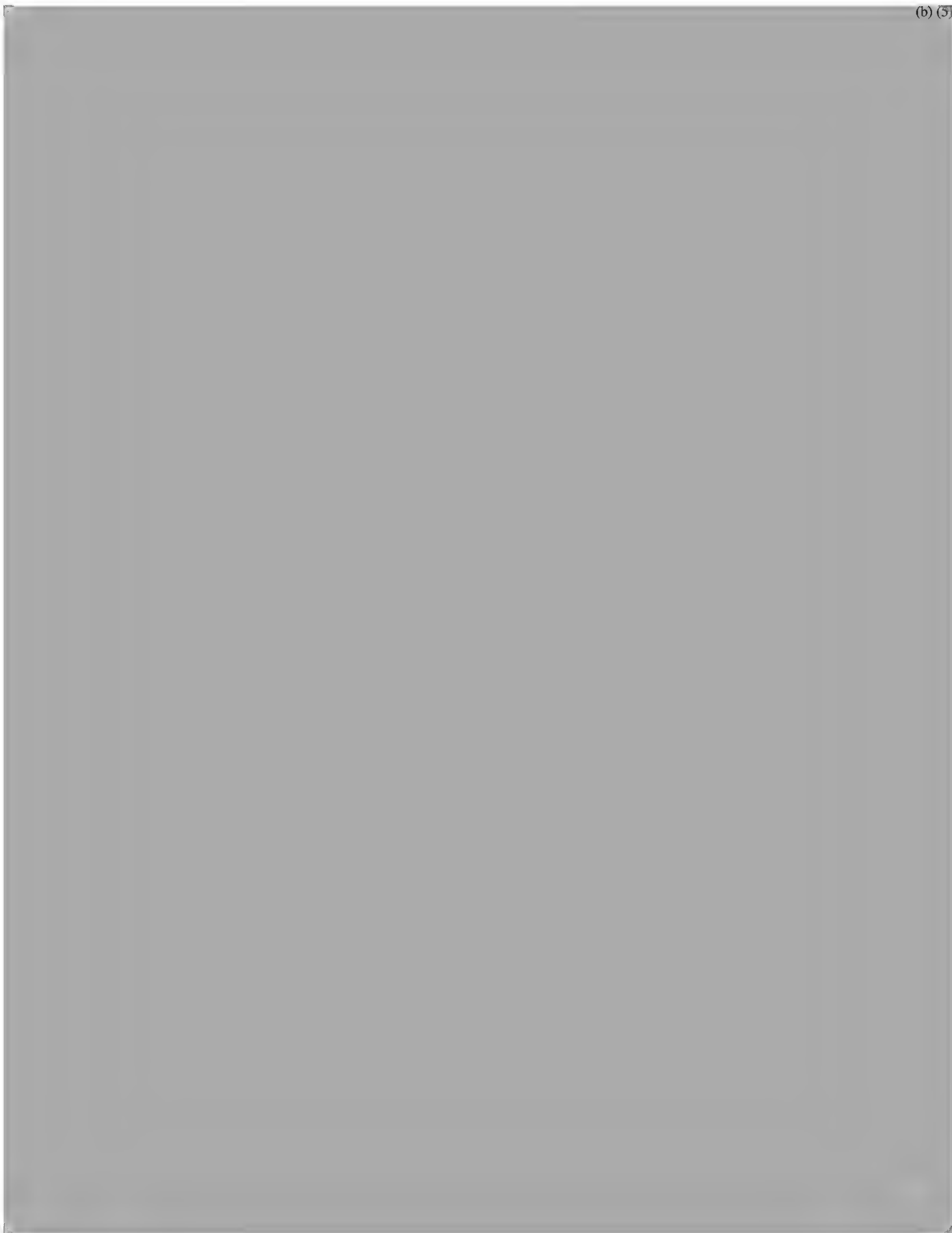




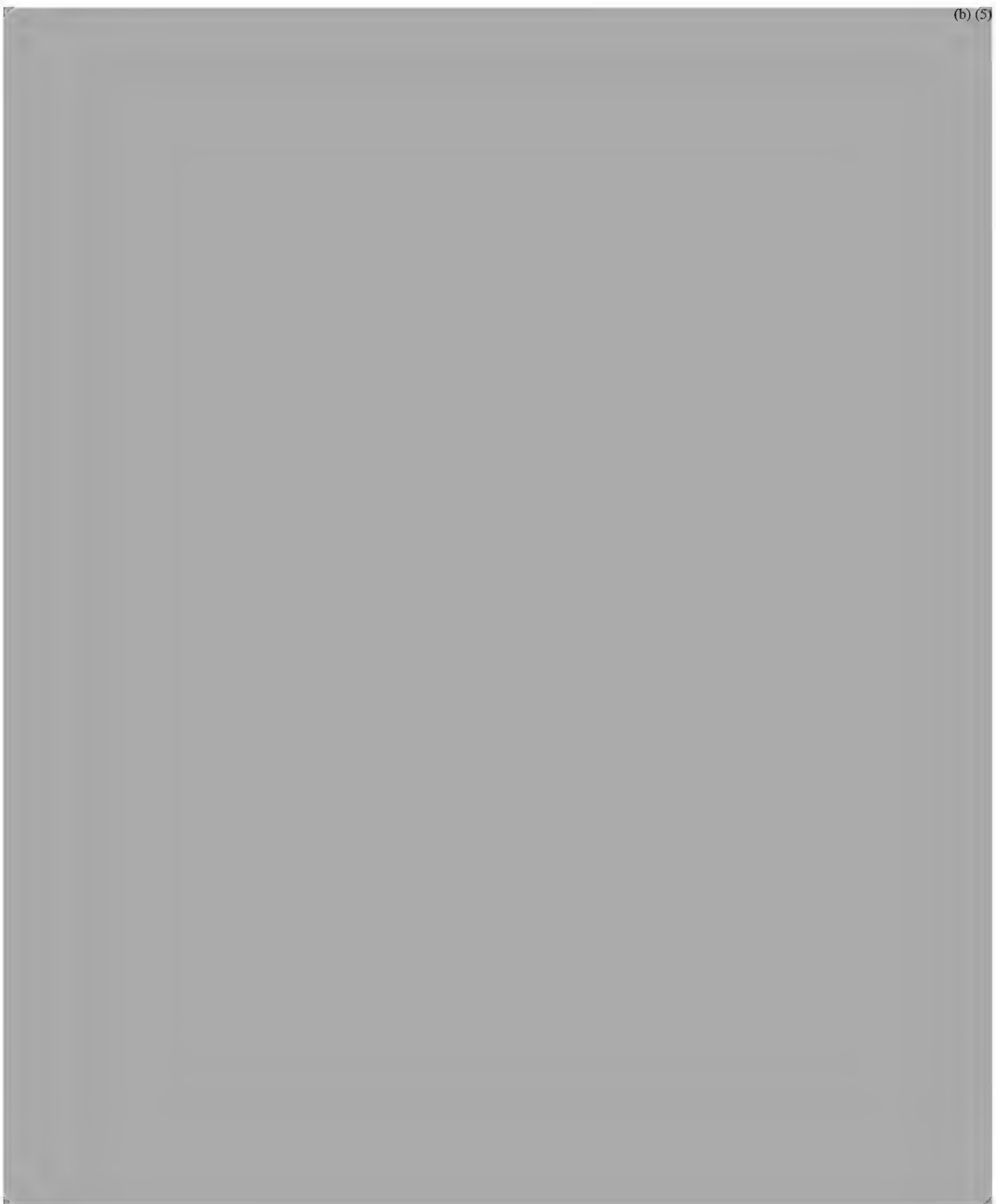
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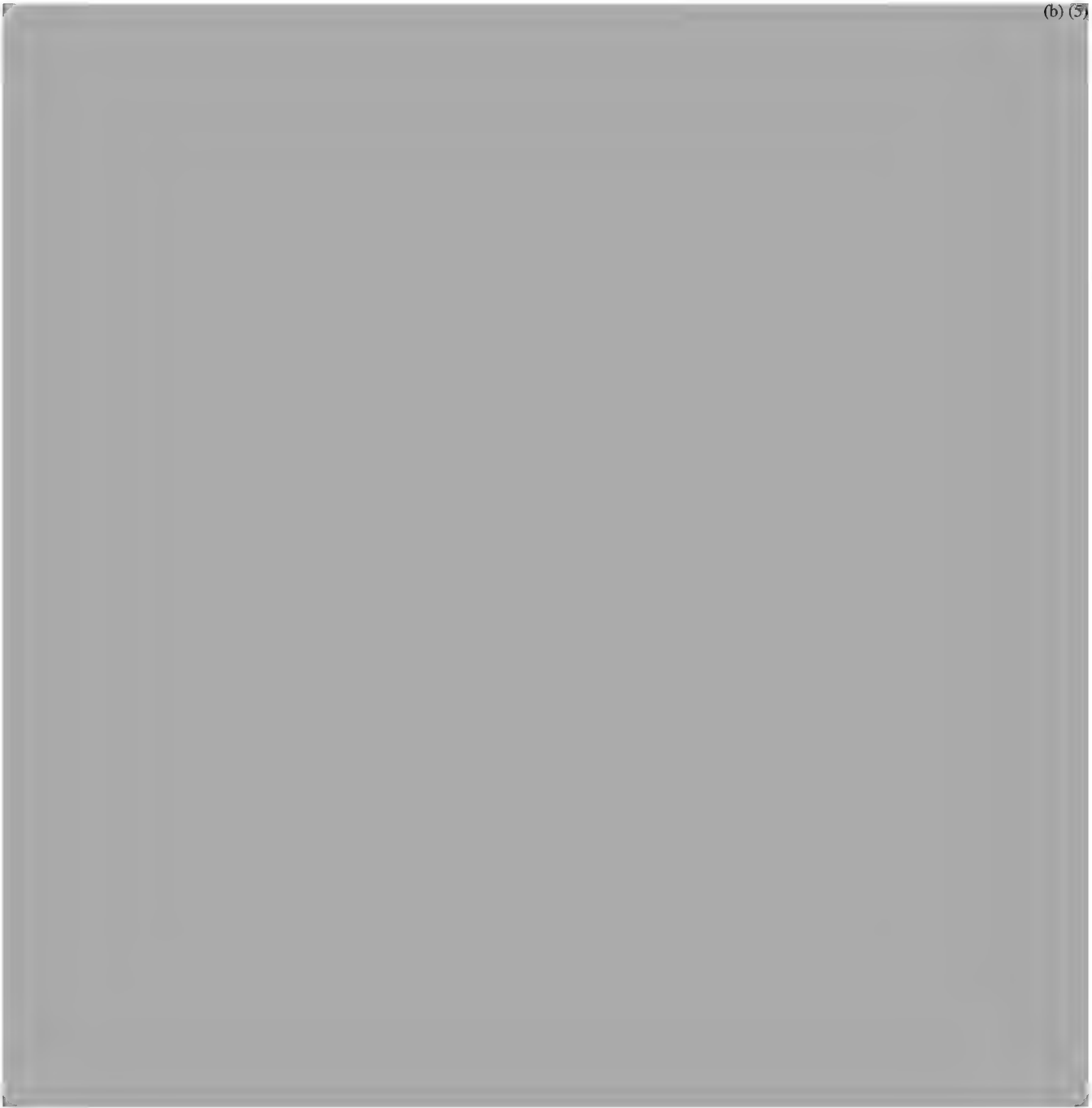
**From:** Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]  
**Sent:** 11/19/2019 7:20:28 PM  
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**Subject:** Exported BRAIN Record (Drug Pricing)  
**Attachments:** Exported BRAIN Record (Drug Pricing).docx











**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 4/10/2020 12:29:52 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Patent Information

Thanks Mark – I met with [b6] some time ago and briefed him on the confidential nature of the information I would be providing to him. Karen

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, April 9, 2020 6:41 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Subject:** RE: Patent Information

Karen: I appreciate your quick return on this. In the future, I think we

[b5]

I don't think

[b5]

[b5]

[b5]

I think

[b5]

**From:** Rohrbaugh, Mark (NIH/OD) [E]

**Sent:** Thursday, April 9, 2020 6:37 PM

**To:** Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>

**Cc:** Maples, Ronald (NIH/OD/ORS) [E] <ronald.maples@nih.gov>; Partin, Kathryn (NIH/OD) [E] <kathryn.partin@nih.gov>

**Subject:** RE: Patent Information

Thanks Karen. Please note that

[b5]

we should

[b5]

[b5]

[b5]

**From:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>

**Sent:** Thursday, April 9, 2020 9:09 AM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

**Cc:** Maples, Ronald (NIH/OD/ORS) [E] <ronald.maples@nih.gov>; Partin, Kathryn (NIH/OD) [E] <kathryn.partin@nih.gov>

**Subject:** RE: Patent Information

Hi Mark – Reports and documents attached.

[b5,b7(A)]

The license garnered the attention of KEI. Let me

know if I can pull any additional information. Regards, Karen

Karen Rogers  
Acting Director  
Senior Royalties Administrator  
Office of Technology Transfer  
6011 Executive Blvd, Suite 325  
Rockville, MD 20852  
Phone: 301-435-4359



**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, April 8, 2020 5:01 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Subject:** FW: Patent Information

Karen:

I don't have access to TTS from home. Could you please

b5,b7(A)

b5,b6,b7(A)

If there is something, please send the list back in a file to me.

Stay healthy  
Mark

**From:** Partin, Kathryn (NIH/OD) [E] <kathryn.partin@nih.gov>  
**Sent:** Wednesday, April 8, 2020 4:35 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Patent Information

Hi Mark,

Do you have any time to take a look at  
which b6 is wondering about.

b5,b6,b7(A)

please see the attached,

Hope you are doing well!

Thanks!  
Kathy

**From:** b6  
**Sent:** Wednesday, April 8, 2020 4:06 PM  
**To:** Partin, Kathryn (NIH/OD) [E] <kathryn.partin@nih.gov>  
**Subject:** Patent Information

Hi Kathy,

I was doing some research on patents and came across this one that peaked my interest.

b5,b7(A)

b5,b7(A)

Thanks,

b6

Office of Security and Emergency Response  
National Institutes of Health  
(office) b6  
(mobile)



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---

**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 9/20/2019 8:13:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Re: Jamie Love: non-profit sponsors include reasonable pricing clause in France. Why not in the US?

What, you mean Jamie Love isn't telling the truth???

On 9/20/2019 3:43 PM, Rohrbaugh, Mark (NIH/OD) [E] wrote:

This is not true. He never said this....

The NIH, however, has statutory responsibility under the Bayh-Dole Act to require that funded inventions be "available to the public on reasonable terms," though NIH Director Francis Collins has decided to leave pricing decisions to drug companies, without any limits.

With a government run health system,, the French govt can do what it wants and most probably has specific authority to negotiate price.

---

**From:** Joe Allen <jallen@allen-assoc.com>  
**Sent:** Friday, September 20, 2019 3:36 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** Jamie Love: non-profit sponsors include reasonable pricing clause in France. Why not in the US?

From STAT News (<https://www.statnews.com/2019/09/18/zolgensma-reasonable-pricing-france/>)  
First Opinion

## Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France

By James Love

September 18, 2019

When a new drug emerges from research largely funded by grants from charities and government agencies, who gets to set the price? In the U.S., that question seems to have been answered — the drug company that makes it. As I've learned from a poorly redacted filing with the Securities and Exchange Commission, the answer may be different in France.

In May, the FDA approved Zolgensma, a gene therapy for young children with spinal muscular atrophy (SMA). Its maker, Novartis (NVS), set the price at \$2.1 million, roughly nine times the median sale price for a home in the U.S. and 33 times the national per capita income.

One explanation for the high price is, why not? Novartis can charge whatever it wants for this therapy, and justifies the high price based on the emotional appeal of treating children with a

terrible disease and a carefully nurtured narrative that new treatments are very expensive to develop.

But there's more to the story. The early development of Zolgensma was financed by the National Institutes of Health, which funded more than \$450 million in grants citing "spinal muscular atrophy," and also by a plethora of charities such as Sophia's Cure, Cure SMA, Getty Owl Foundation, Fighting SMA, Jadon's Hope Foundation, the Gwendolyn Strong Foundation, and Miracle for Madison — and those are just the ones in the U.S. — that are devoted to finding treatments for SMA. These charities called upon patient families and friends to subsidize the early research and clinical trials.

Sophia's Cure at one point sued Nationwide Children's Hospital for failing to provide the recognition it had been promised for its role as a sponsor of the investigational therapy.

None of the U.S. charities placed conditions on their grants about pricing if a drug did eventually make it to the market.

The NIH, however, has statutory responsibility under the Bayh-Dole Act to require that funded inventions be "available to the public on reasonable terms," though NIH Director Francis Collins has decided to leave pricing decisions to drug companies, without any limits.

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When I looked at the file, I noticed that the redactions were flawed, and that only the background color of the redacted parts had been changed. It was simple to load the document into a word processor, change the background colors, and create a completely unredacted version.

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“Following the appropriate regulatory approvals, Licensee will use Reasonable Efforts to make available within France all the Licensed Products indicated for SMA at prices that would allow appropriate reimbursement scheme and that would not constitute an obstacle for patients to have access to the therapy. Licensee shall be solely responsible for designing and conducting all Commercialization activities necessary to fulfill its obligations under this Section.”

In the U.S., government, private, and public health insurance providers are limiting coverage for Zolgensma because of its record-breaking and access-blocking price. It could be a different story in France, depending upon what Généthron is prepared to do with the leverage it has in its license.

This raises a huge question for U.S. charities and government funding agencies: Why don't our tax-exempt charities insist on reasonable pricing agreements to protect access to the medicines they help make, and why does the NIH refuse to enforce the contractual obligations in funding agreements to make the benefits of government inventions "available to the public on reasonable terms?"

*James Love is director of Knowledge Ecology International, a not-for-profit organization that advocates for access to medical treatments at affordable prices, and is currently a member of the board of directors of the Union for Affordable Cancer Treatment. Knowledge Ecology International and the Union for Affordable Cancer Treatment have both petitioned the NIH and other federal agencies to use their rights regarding federally funded inventions to curb excessive prices. Both organizations are funded by private donations and do not accept funding from the pharmaceutical industry.*

## About the Author

**James Love**

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[@jamie love](#)

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This photo provided by Novartis shows its gene therapy medicine, Zolgensma. *Novartis via AP*

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(W) 740-484-1814  
(c) b6  
[www.allen-assoc.com](http://www.allen-assoc.com)

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**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 1/7/2020 4:29:36 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]  
**Subject:** Re: Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

I suggest b5

---

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Date:** Tuesday, January 7, 2020 at 10:39:33  
**To:** "Shmilovich, Michael (NIH/NHLBI) [E]" <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Subject:** Fwd: Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

I was too quick with the trigger finger and I cannot pull it back from home

Sent from my iPhone

Begin forwarded message:

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Date:** January 7, 2020 at 10:38:17 AM EST  
**To:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Subject:** Re: Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

I suggest not answering

Sent from my iPhone

On Jan 7, 2020, at 10:35 AM, kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)> wrote:

Dear Mr. Shmilovich:

Thank you for your prompt response.

I was hoping you could clarify your answers to Questions 3 and 4.

Question 3 asked how the NIH fulfilled its statutory mandate to determine that exclusivity was a necessary incentive. Your answer cited the target disease and its prevalence, which you state is available online. KEI has researched XLRS and is aware of its low prevalence. I understand your response to mean that NIH considered only those factors when deciding to grant exclusivity. **Please let me know if that understanding is incorrect and what, if any, other factors were considered.** Also, please note that the license as described in the FR is not limited to XLRS. The second invention covered by the license is described as "Potentially curative therapy for XLRS, **retinoschisis, age-related macular**

**degeneration, diabetic retinopathy, Leber congenital amaurosis, retinal detachment, cysts, cystoid, macular edema, retinitis pigmentosa, and senile schisis" and the field of use described in the FR is not limited to XLRS - it extends to "schisis cavity associated ocular disease or injury."** How does your answer account for the other disease indications?

Per Question 4, you referred KEI to Dr. Rohrbaugh's statements in his November 26, 2019 letter which refer to **two other licenses**. Please note that Question 4 is specific to the NIH's analysis of **this license**. Also, you call this technology "early stage." Please clarify how you define early stage. According to the PhRMA, typical drug development proceeds through four phases: (1) basic research, (2) preclinical trials, (3) clinical trials, and (4) FDA New Drug Application (NDA) filing and approval. As you know, this invention has proceeded past basic discovery and preclinical trials, and based on preclinical trial results, an IND was submitted and the invention proceeded to a **Phase I/IIa clinical trial** that has already reported some positive preliminary results. How does this meet the definition of early stage?

**Finally, why is the analysis the same for this invention as those covered by the Nov. 26 letter? As far as I understand, the inventions discussed in the letter had not been investigated in human clinical trials at the time the license was noticed, so they had a different stage of development.**

Thank you in advance for your consideration.

On Tue, Jan 7, 2020 at 8:58 AM Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> wrote:

Dear Ms. Ardizzone:

Regarding your email. Our responses are shown below in blue:

Dear Mr. Shmilovich:

Thank you for answering my colleague Luis Abinader's questions regarding the proposed license to OcQuila. I have a few questions about the licensed inventions.

1. The clinical trial NCT02317887, Study of RS1 Ocular Gene Transfer for X-linked Retinoschisis, investigated the first invention listed in the notice. **Will the second invention, Newly Improved Method and Composition for Treating Genetically Linked Diseases of the Eye, be**

**investigated in any clinical trials, including NCT02317887?** So far, it appears that it has only been studied in mice, yet the development stage for the invention is listed as "clinical" in this licensing opportunity notice.

That is not known at this time and will be up to the licensee and NEI.

2. Can you provide us a copy of the unpublished patent applications associated with the second invention? This is not confidential business material and will help us to evaluate the license.

The PCT application has not yet published yet. Under our policy, until a PCT application is published, it is only available under a Confidential Disclosure Agreement.

3. You told Mr. Abinader that NIH is not required to perform an economic analysis to determine that an exclusive license is appropriate. **What analysis, if any, did you undergo before deciding to propose an exclusive license? If you determined that exclusivity was necessary, on what basis did you so conclude?**

XLRS is a rare disease and information about its incidence is readily available.

4. Dr. Mark Rohrbaugh, Special Advisor for Technology Transfer to the NIH Deputy Director for Intramural Research, has publicly stated that **"[t]he closer a technology is to the marketplace, the lower the risk and cost to the licensee, and the more valuable the technology from a royalty standpoint."** Mark L. Rohrbaugh, NIH: Moving Research from the Bench to the Bedside, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, July 10, 2003, <https://www.govinfo.gov/content/pkg/CHRG-108hhrg88429/html/CHRG-108hhrg88429.htm>. **How is the NIH negotiating this license in a way that reflects that commercial potential of these inventions? Are all inventions treated equally per NIH's licensing practices regardless of development stage, risk, and cost?**

The value of patent commercialization licenses are not uniform and depend on many factors including the state of development. The present invention is early stage. Negotiation of a license, including royalties, does not occur until a final decision is made based on any competing applications and comments submitted during the notice period. The question has also been previously answered in Dr. Rohrbaugh's November 26, 2019 letter (enclosed), and the answer in that letter applies to the current case as well.

Regards,

Michael A. Shmilovich, Esq., CLP

<image001.jpg>  
Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
o. 301.435.5019

[shmilovm@nih.gov](mailto:shmilovm@nih.gov)

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**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Monday, January 6, 2020 2:37 PM

**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

Dear Mr. Shmilovich:

REL0000025136



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Thank you in advance for your consideration.

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

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[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

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**Sent:** 9/20/2019 7:36:00 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Jamie Love: non-profit sponsors include reasonable pricing clause in France. Why not in the US?

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By James Love

September 18, 2019

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## About the Author

**James Love**

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[@jamie\\_love](#)

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This photo provided by Novartis shows its gene therapy medicine, Zolgensma. *Novartis via AP*

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**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 1/7/2020 1:56:56 PM  
**To:** Kathryn Ardizzone [kathryn.ardizzone@keionline.org]; Luis Gil Abinader [luis.gil.abinader@keionline.org]; Jamie Love [james.love@keionline.org]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** RE: Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169  
**Attachments:** KEI appeal response 11262019.pdf

Dear Ms. Ardizzone:

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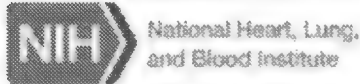
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Regards,

Michael A. Shmilovich, Esq., CLP



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Bethesda, MD 20892-2479  
o. 301.435.5019  
[shmilovm@nih.gov](mailto:shmilovm@nih.gov)

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**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Monday, January 6, 2020 2:37 PM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

Dear Mr. Shmilovich:

Thank you for answering my colleague Luis Abinader's questions regarding the proposed license to OcQuila. I have a few questions about the licensed inventions.

1. The clinical trial NCT02317887, Study of RS1 Ocular Gene Transfer for X-linked Retinoschisis, investigated the first invention listed in the notice. **Will the second invention, Newly Improved Method and Composition for Treating Genetically Linked Diseases of the Eye, be investigated in any clinical trials, including NCT02317887?** So far, it appears that it has only been studied in mice, yet the development stage for the invention is listed as "clinical" in this licensing opportunity notice.

2. Can you provide us a copy of the unpublished patent applications associated with the second invention? This is not confidential business material and will help us to evaluate the license.

3. You told Mr. Abinader that NIH is not required to perform an economic analysis to determine that an exclusive license is appropriate. **What analysis, if any, did you undergo before deciding to propose an exclusive license? If you determined that exclusivity was necessary, on what basis did you so conclude?**

4. Dr. Mark Rohrbaugh, Special Advisor for Technology Transfer to the NIH Deputy Director for Intramural Research, has publicly stated that "[t]he closer a technology is to the marketplace, the lower the risk and cost to the licensee, and the more valuable the technology from a royalty standpoint." Mark L. Rohrbaugh, NIH: Moving Research from the Bench to the Bedside, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, July 10, 2003, <https://www.govinfo.gov/content/pkg/CHRG->

108hhrg88429/html/CHRG-108hhrg88429.htm. **How is the NIH negotiating this license in a way that reflects that commercial potential of these inventions? Are all inventions treated equally per NIH's licensing practices regardless of development stage, risk, and cost?**

Thank you in advance for your consideration.

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670



**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 1/6/2020 8:51:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** Re: NIH response to KEI letter re Ocquila

Not sure what you mean. I thought [REDACTED] b5

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Date:** Monday, January 6, 2020 at 15:47:19  
**To:** "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Goldstein, Bruce (NIH/NHLBI) [E]" <goldsteb@mail.nih.gov>, "Berkley, Dale (NIH/OD) [E]" <berkleyd@od.nih.gov>  
**Subject:** RE: NIH response to KEI letter re Ocquila

Why [REDACTED] b5 why not [REDACTED] b5 ?

Also, you need to [REDACTED] b5  
[REDACTED] b5

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Monday, January 6, 2020 10:41 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** NIH response to KEI letter re Ocquila

Dear Mark, Dale, and Bruce --  
Happy New Year!

[REDACTED] b5  
[REDACTED] b5 [REDACTED] b5 Last time we discussed [REDACTED] b5  
[REDACTED] b5 Moreover, [REDACTED] b5  
[REDACTED] b4,b5 As such, [REDACTED] b5  
[REDACTED] b5

Regards,

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
o. 301.435.5019  
shmilovm@nih.gov

REL0000025140

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**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 9/18/2019 5:20:09 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Lyell

Yes, I agree that we should

b5

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, September 18, 2019 12:34 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Fwd: Lyell

I don't

b5

b5

Should we

b5

b5

Sent from my iPhone

Begin forwarded message:

**From:** "Knabb, Jim (NIH/NCI) [E]" <jim.knabb@nih.gov>  
**Date:** September 18, 2019 at 12:26:24 PM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Subject:** FW: Lyell

Hi Mark,

Additional follow up from KEI re: E-106-2015 and E-017-2017 (which we've previously discussed). I don't know what the angle is, but happy to discuss what a proper response would be.

Best,  
Jim

**From:** James Love <james.love@keionline.org>  
**Sent:** Wednesday, September 18, 2019 12:11 PM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>; Kathryn Ardizzone <kathryn.ardizzone@keionline.org>  
**Subject:** Lyell

Dear Jim,

As regards the Lyell licenses, why is this license being done before the all of the patent applications are published and before there are results from the trials the NIH is funding?

REL0000025141

Is there an expectation that Lyell will begin a new clinical trial or register the treatment sooner if the NIH licenses this now, instead of when results are known from the trials?

Jamie

--

James Love. Knowledge Ecology International

U.S. Mobile +1.202.361.3040

U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 10/28/2019 10:52:47 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Stackhouse, Thomas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7e1c23441b64258803cab5e97db8270-stackhot]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgr]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]  
**Subject:** Fwd: Administrative Appeal, Exclusive Patent License in "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc.  
**Attachments:** Attachment A.pdf; ATT00001.htm; Attachment B.pdf; ATT00002.htm; Attachment C.pdf; ATT00003.htm; Attachment D.pdf; ATT00004.htm; Attachment E.pdf; ATT00005.htm; Attachment F.pdf; ATT00006.htm; Attachment G.pdf; ATT00007.htm; Attachment H.pdf; ATT00008.htm; Attachment I.pdf; ATT00009.htm; Attachment J.pdf; ATT00010.htm; Attachment K.pdf; ATT00011.htm; Joint Administrative Appeal, NIH Exclusive License to Intima Bioscience (2).pdf; ATT00012.htm

Good Morning Mark and Dale - Looks like we have another Administrative Appeal. Please advise. Regards,  
Karen

Sent from my iPhone

Begin forwarded message:

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Date:** October 26, 2019 at 5:30:45 PM EDT  
**To:** <rogersk@mail.nih.gov>  
**Cc:** James Love <james.love@keionline.org>, <manon.ress@cancerunion.org>, Peter Maybarduk <pmaybarduk@citizen.org>, Steve Knievel <sknievel@citizen.org>, Alex Lawson <alawson@socialsecurityworks.org>, Ruth Lopert <ruth.lopert@gmail.com>, <lovesplumbing@comcast.net>  
**Subject:** Administrative Appeal, Exclusive Patent License in "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc.

Dear Ms. Rogers:

Attached, please find the joint administrative appeal of the NIH's decision to proceed with an exclusive patent license in "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc. as described in the Federal Register at 84 FR 45503, as well as the associated attachments, submitted today by Knowledge Ecology International, Union for Affordable Cancer Treatment, Public Citizen, Social Security Works, LWC Health, Ruth Lopert, Manon Ress, and Terry Love

Thank you in advance for your consideration of the appeal.

Sincerely,

Kathryn Ardizzone, Esq.

REL0000025143

Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@kcionline.org](mailto:kathryn.ardizzone@kcionline.org)  
(202) 332-2670





kathryn ardizzone <kathrynardizzonekei@gmail.com>

---

## Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

---

Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Tue, Sep 10, 2019 at 3:59 PM

To: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

### Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Monday, September 9, 2019 12:30 PM

**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

**Cc:** Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

**Subject:** Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

REL0000025143.0001

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical
  - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
2. If the government has provided funding:
  0. How much has been spent by the government on these trials? Answer: The technologies are preclinical.
  - a. Please identify any NIH grant numbers.
  - b. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.
3. Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement Answer: This has not yet been determined.
  0. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
5. According to the Federal Register notice, Intima Bioscience is "headquartered in New York." According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name "Intima Bioscience" using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name "Intima Capital" using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is "Intima Bioscience" or "Intima Capital." Answer: The applicant is Intima Bioscience, Inc.
6. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled "Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer"? Answer: Yes, the applicant is the same.
  0. Was the exclusive license described in 80 FR 59790 executed? Answer: No
  - a. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
7. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.
8. Does Intima Bioscience has a website? If so, please provide a link to their website. Answer: I am not aware of a website for Intima Bioscience, Inc.
  0. Note that "Intima Capital," a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
  - a. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in "Gene Engineering for Cancer Therapy" was funded by Intima Capital LLC.
  - b. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
9. Please confirm whether the following CRADA is associated with the licensed technology:
  0. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.
  - a. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.
10. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"? Answer: No



0. If "Yes," please provide a citation for the listing(s).

11. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.
12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

[Quoted text hidden]



kathryn ardizzone <kathrynardizzonekei@gmail.com>

---

## Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

---

kathryn ardizzone <kathrynardizzonekei@gmail.com>

Wed, Sep 11, 2019 at 12:59 PM

To: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Thank you, Andy.

Can you please answer our question about Intima Bioscience's principals/list the members of its board of directors? We believe that is not too much to ask, considering that this information is not publicly-available, and Intima Bioscience apparently is not even registered to do business in the state in which it is headquartered. We need this information to effectively comment on the licenses.

Thanks,

Kathryn

[Quoted text hidden]

...

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

REL0000025143.0003



kathryn ardizzone <kathrynardizzonekei@gmail.com>

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**Questions Re: Prospective Grant of an Exclusive Patent License:  
Genetically-Modified Lymphocytes for Cancer Therapy**

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**Burke, Andy (NIH/NCI) [E]** <andy.burke@nih.gov>

Wed, Sep 11, 2019 at 1:40 PM

To: kathryn ardizzone <kathrynardizzonekei@gmail.com>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Dear Ms. Ardizzone,

I am unable to release this information. You may, however, request it directly from the company.

Regards,

Andy

[Quoted text hidden]

REL0000025143.0005



kathryn ardizzone <kathrynardizzonekei@gmail.com>

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**Questions Re: Prospective Grant of an Exclusive Patent License:  
Genetically-Modified Lymphocytes for Cancer Therapy**

---

kathryn ardizzone <kathrynardizzonekei@gmail.com>

Wed, Sep 11, 2019 at 2:29 PM

To: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Dear Dr. Burke:

Thank you for your response.

Given the lack of publicly-available data about the company (no website, no registration in NY, no officers or contact information for those officers listed in Delaware corporate records), how do you propose that KEI request this information directly from the company?

Also, please clarify why you are unable to release this information.

Finally, please explain how the public can be ensured that Intima Bioscience, Inc. is an appropriate licensee, who can bring the invention to market, without even knowing who its principals are, and without the ability to contact them directly for that information.

Thank you,  
Kathryn Ardizzone

[Quoted text hidden]

REL0000025143.0007



kathryn ardizzone <kathrynardizzonekei@gmail.com>

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## Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

---

**Burke, Andy (NIH/NCI) [E]** <andy.burke@nih.gov>

Wed, Sep 11, 2019 at 4:45 PM

To: kathryn ardizzone <kathrynardizzonekei@gmail.com>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

**From:** kathryn ardizzone <kathrynardizzonekei@gmail.com>

**Sent:** Wednesday, September 11, 2019 2:29 PM

**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

**Cc:** Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

**Subject:** Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Thank you for your response.

Given the lack of publicly-available data about the company (no website, no registration in NY, no officers or contact information for those officers listed in Delaware corporate records), how do you propose that KEI request this information directly from the company? Answer: The company's mailing address is publicly-available, as is a phone number. Please see, for example, <https://start.cortera.com/company/research/l6o5lxm2r/intima-bioscience-inc/>.

Also, please clarify why you are unable to release this information. Answer: Please see 37 CFR 404.14

[Quoted text hidden]

[Quoted text hidden]

REL0000025143.0009



kathryn ardizzone <kathrynardizzonekei@gmail.com>

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## Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

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kathryn ardizzone <kathryn.ardizzone@keionline.org>  
To: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>

Thu, Sep 12, 2019 at 5:47 PM

Dear Dr. Burke,

Thank you for your email.

I apologize if my question was not clearly stated. I understand your previous statement that no Licensing Opportunity Notices were published concerning E-171-2018, E-173-2018, E-174-2018. I concluded as much when I entered those numbers on the search engine and it returned no results. What I am asking is **why the NIH chose not to publish a licensing opportunity notice with respect to the inventions**. It seems intuitive that publishing the Licensing Opportunity notice on OTT's website would draw in the greatest possible number of license applicants, and thus help fulfill NIH's desire to "improve the chances that the technologies will be made available to the public." It could also increase the chances that the NIH negotiates publicly-favorable licensing terms. **Why did the NIH not publish Licensing Opportunity Notices regarding these inventions?**

With regards to your statement about 37 CFR 404.14 preventing NIH from identifying the principals of Intima Bioscience, please note that 37 CFR 404.14 pertains only to "any **plan** submitted pursuant to § 404.8(h)." 37 CFR 404.8(a) lists several components of a license application, of which a development plan is only one. The other elements are not confidential under 37 CFR 404.14.

KEI called Intima Bioscience, and was not able to connect with anyone who could tell us who its principals are. If you disclose that non-confidential information to us in advance of the comment deadline tomorrow, that would be helpful.

Thank you,  
Kathryn Ardizzone

[Quoted text hidden]

REL0000025143.0011



kathryn ardizzone &lt;kathrynardizzonekei@gmail.com&gt;

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**Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503**

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kathryn ardizzone &lt;kathryn.ardizzone@keionline.org&gt;

Thu, Sep 26, 2019 at 4:42 PM

To: "Burke, Andy (NIH/NCI) [E]" &lt;andy.burke@nih.gov&gt;

Dear Dr. Burke,

Thank you for forwarding the NCI's final determination regarding KEI's comments on the license to Intima Bioscience.

Is the period of exclusivity for the subject license life of patent? Please let us know, as this pertains to a possible basis on which we may appeal the determination.

Sincerely,

Kathryn Ardizzone

[Quoted text hidden]

—

[Quoted text hidden]



kathryn ardizzone &lt;kathrynardizzonekei@gmail.com&gt;

---

**Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503**

---

**Burke, Andy (NIH/NCI) [E]** <andy.burke@nih.gov>

Fri, Sep 27, 2019 at 9:23 AM

To: kathryn ardizzone &lt;kathryn.ardizzone@keionline.org&gt;

Dear Ms. Ardizzone,

Please refer to my email of September 10 where this questions is addressed.

Regards,

Andy

[Quoted text hidden]





kathryn ardizzone &lt;kathrynardizzonekei@gmail.com&gt;

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**Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503**

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kathryn ardizzone &lt;kathryn.ardizzone@keionline.org&gt;

Fri, Sep 27, 2019 at 9:39 AM

To: "Burke, Andy (NIH/NCI) [E]" &lt;andy.burke@nih.gov&gt;

Cc: James Love &lt;james.love@keionline.org&gt;

Dear Dr. Burke,

Thank you for your email. I have referred to your September 10 email where the question is addressed. It states:

Question: Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement.

**Answer: This has not yet been determined.**

Since September 10, 17 days have passed, and the NCI has rejected KEI's comments and determined that the license is appropriate. As you are aware, under Section 209 of the Bayh Dole Act, this requires that NCI has determined that the scope (including term) of the license is not greater than reasonably necessary. So, presumably something should have changed since your September 10 email.

I will pose the question to you again: Has the NCI established the duration of the prospective license to Intima Bioscience?

A "yes" or "no" answer would be responsive, and it would be appreciated.

If your answer is "yes," what is the term?

If your answer is "no," when do you anticipate making such a determination?

Thank you in advance for your assistance with these questions.

Kathryn Ardizzone

[Quoted text hidden]



kathryn ardizzone &lt;kathrynardizzonekei@gmail.com&gt;

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**Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503**

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**Burke, Andy (NIH/NCI) [E]** <andy.burke@nih.gov>  
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Fri, Sep 27, 2019 at 11:06 AM

Dear Ms. Ardizzone,

I referred you to my previous response because that answer remains correct. As you know from past correspondence with my office, the term of a license is a product of negotiation and is therefore not fixed until the agreement is executed. As you are also aware, the terms of an executed license are business confidential information.

Regards,

Andy

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, September 27, 2019 9:39 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke,

Thank you for your email. I have referred to your September 10 email where the question is addressed. It states:

**Question:** Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement.

**Answer:** This has not yet been determined.

Since September 10, 17 days have passed, and the NCI has rejected KEI's comments and determined that the license is appropriate. As you are aware, under Section 209 of the Bayh Dole Act, this requires that NCI has determined that the scope (including term) of the license is not greater than reasonably necessary. So, presumably something should have changed since your September 10 email.

I will pose the question to you again: Has the NCI established the duration of the prospective license to Intima Bioscience? Answer: No

A "yes" or "no" answer would be responsive, and it would be appreciated.

If your answer is "yes," what is the term?

If your answer is "no," when do you anticipate making such a determination? Answer: Currently unknown, since the timeline of negotiation is determined as much by the responsiveness of the counterparty as it is by the NCI.

[Quoted text hidden]

[Quoted text hidden]



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October 26, 2019

Karen Rogers  
Acting Director  
NIH Office of Technology Transfer  
6011 Executive Blvd, Suite 325  
Rockville, MD 20852  
Via Email: [rogersk@mail.nih.gov](mailto:rogersk@mail.nih.gov)

**Re: Administrative Appeal, Exclusive Patent License in “Genetically-Modified Lymphocytes for Cancer Therapy” to Intima Bioscience, Inc.**

Dear Ms. Rogers:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen, Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love (collectively, “Appellants”), write to appeal the decision of the National Institutes of Health (NIH) to grant an exclusive license in “Genetically-Modified Lymphocytes for Cancer Therapy” to Intima Bioscience, Inc. as described in the Federal Register at 84 FR 45503<sup>1</sup> (“the Notice”).

The licensed inventions are T-cell therapies with potential indications in diseases such as breast cancer, gastrointestinal epithelial cancer, lung cancer, and B cell lymphoma. Given the broad reach of the inventions and their potential importance to public health outcomes, it is concerning that almost no information is publicly-available about the prospective licensee. Intima Bioscience is not registered to conduct business in New York, the state where it is headquartered according to the Notice, and it does not maintain a website. With a prospective licensee as obscure as Intima Bioscience, the NIH should be particularly transparent about the license. As always, any license that the NIH negotiates must comply with the criteria located at 35 U.S.C. § 209(a).

Unfortunately, the cursory statements contained in the NIH’s response to our comments indicate that the NIH has not engaged in the analysis mandated by 35 U.S.C. § 209(a), nor has it given

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<sup>1</sup> 84 Fed. Reg. 45503 (Aug. 29, 2019), available at <https://www.federalregister.gov/documents/2019/08/29/2019-18648/prospective-grant-of-an-exclusive-patent-license-genetically-modified-lymphocytes-for-cancer-therapy>.

any serious consideration to our objections. Moreover, the NIH cannot demonstrate that an exclusive license was necessary in this instance because it did not publicly announce the subject inventions as available for licensing.

Finally, the NIH's lack of transparency regarding information relevant to the license and how it performed the requisite analysis continues a concerning trend in which the NIH is exhibiting an increasing lack of respect for the public's right to comment on its licensing decisions.

This appeal addresses five issues:

1. Did the NIH properly evaluate the necessity of granting an exclusive license in the subject inventions, as it is required to do under 35 U.S.C. § 209(a)(1)?
2. Assuming that the NIH can establish that an exclusive license was necessary in this case, did the NIH meet its statutory responsibility to limit the scope of rights to that which is "reasonably necessary" to induce the investment required to bring the invention to practical application, as required by 35 U.S.C. § 209(a)(2)?
3. Has the NIH withheld relevant, nonconfidential information about the license from the public, impeding its right to comment under 35 U.S.C. § 209(e)?
4. Did the NIH request the antitrust advice of the Attorney General, pursuant to 40 U.S.C. § 559?
5. Has the NIH implemented the objectives in the Public Health Service (PHS) Technology Transfer Policy Manual regarding promoting access in developing countries?

We request a hearing on this appeal.

## **A. BACKGROUND AND PROCEDURAL HISTORY**

### *The Inventions and Prospective Licensee*

The Notice associated with the license, 84 FR 45503, lists 33 patents/patent applications, which are grouped into four categories:

- Group A: Intracellular Genomic Transplant and Methods of Therapy;
- Group B: Modified Cells and Methods of Therapy;
- Group C: Viral Methods of T Cell Therapy; and
- Group D: CAS9 Modified TIL for Treatment of Gastrointestinal Cancer.

According to the patent documents, the inventions seek to overcome a major limitation in cancer immunotherapies: the fact that their "successes have been limited largely to hematological



The Notice refers to the prospective licensee as "Intima Bioscience, Inc. ('Intima'), headquartered in New York, NY."

The statements<sup>5</sup> on the one page website for Intima Capital should also remind the NIH that nowhere is there an expectation that the inventions will be made “available to the public on reasonable terms.”

The investment strategy is predicated on the understanding that healthcare is an investible sector that is fundamentally non-discretionary, uniquely inefficient, and disproportionately requires specific scientific and clinical domain expertise.

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<http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=/netahtml/PTQ/srchnum.html&r=1&f=G&l=50&s=20190008899.PG.NR.&OS=DN/20190008899&RS=DN/20190008899>  
9 (Group D).

3 *Id.*

<sup>4</sup> <https://web.archive.org/web/20190912202840/http://intimacapital.com/>.

<sup>5</sup> <https://web.archive.org/web/20190912202840/http://intimacapital.com/>.

The firm is focused on identifying long-term secular, economic, and scientific trends and then establishing [sic] discrete long/short public equity, derivative, and opportunistic private equity investments to express a proprietary understanding of the field.”<sup>6</sup>

The inventions are co-owned by the United States of America, Regents of the University of Minnesota, and Intima Bioscience, Inc. The inventors listed on the U.S. patents/patent applications correspond to the co-owners of the inventions: Steven Rosenberg, Douglas Palmer, and Nicholas Restifo are scientists with the National Cancer Institute (NCI). Branden Moriarity, Beau Webber, and R. Scott McIvor are researchers with the University of Minnesota’s Masonic Cancer Center. Modassir Choudhry appears to be the founder of Intima Capital.<sup>7</sup>

#### Proposed Scope of the License

The Notice states that “prospective exclusive license territory may be worldwide[.]”

Four fields of use for the prospective license are listed, all of which involve autologous or allogeneic administration of T-cells that were genetically engineered using methods such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) or Adeno-Associated Viral (AAV) vectors to treat diseases such as gastrointestinal epithelial cancer, lung cancer, breast cancer, and B-cell lymphoma in humans.

The Notice does not state the proposed duration of the license.

#### Correspondence about the License

On September 9, 2019, KEI emailed a list of questions about the license to Andrew Burke, Ph.D., a Senior Technology Transfer Manager with the NCI and the point of contact for the license. He responded by email dated September 10, 2019, in which he answered some, but not all, of KEI’s questions.<sup>8</sup>

KEI and Dr. Burke later corresponded further about the NIH’s refusal to disclose the identity of Intima Bioscience’s principals or officers and the duration of the license.<sup>9</sup>

#### Joint Comments

On September 13, 2019, KEI, UACT, Public Citizen, SSW, LWC Health, Ruth Lopert, Manon Ress, and Terry Love (collectively, “the joint commenters”) timely submitted comments on the license, via PDF attachment, in an email to Dr. Burke. The joint comments objected to the license on the grounds that the NIH failed to conduct the analysis for granting an exclusive

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<sup>6</sup> <https://web.archive.org/web/20190912202840/http://intimacapital.com/>.

<sup>7</sup> <https://www.hfalert.com/search.pl?ARTICLE=161015&SEARCH=&PAGE=350&PROPERTY=>.

<sup>8</sup> See Attachment A.

<sup>9</sup> See Attachments B - J.

license under 35 U.S.C. §§ 209(a)(1)&(2), withheld relevant, non-confidential information about the license, impeding the public's right to comment under 35 U.S.C. § 209(e), and failed to seek the antitrust advice of the U.S. Attorney General concerning the disposition of the government's rights in the intellectual property, as required under 40 U.S.C. § 559.

The comments argued further that in the event that the NIH executes the license over the objections stated therein, the license agreement should incorporate a series of provisions designed to implement the policy objectives of the Bayh-Dole Act and the governing principles of the PHS Technology Transfer Manual.

### Final Determination Letter

On September 26, 2019, Dr. Burke emailed KEI the NIH's final response letter regarding the joint comments, which KEI then forwarded to the other commenters.

The body of the letter states in its entirety:

Thank you for providing us with your comments regarding the above-referenced notice ('Notice'). As you indicated your comments were submitted on behalf of several organizations and individuals, we kindly request that you share your response with these same parties.

Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.<sup>10</sup>

Pursuant to the NIH's OTT's appeals procedures, an administrative appeal regarding the license must be submitted within 30 days of the NIH's transmission of the final response letter<sup>11</sup> (no later than October 26, 2019 for the instant license).

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<sup>10</sup> See Attachment K.

<sup>11</sup> The URL for NIH's appeals procedures,

<https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf>, is still nonfunctional. KEI brought this issue to the NIH's attention in early 2018.



## B. STANDING

A right to appeal an exclusive patent license in federally-owned technology is afforded to: “(1) A person whose license has been denied; (2) A licensee whose license has been modified or terminated, in whole or in part; or (3) A person who timely filed a written objection in response to the notice . . . and who can demonstrate . . . that such person may be damaged by the agency action.” 37 C.F.R. § 404.11(a).

Appellants satisfy the third basis for an appeal. We timely submitted our comments to the NIH, and appellants Terry Love and Manon Ress are cancer patients who could be damaged by the license. An overly broad exclusive license that is inconsistent with 35 U.S.C. § 209 not only violates federal law but could harm patients, such as Mr Love and Ms Ress, who may need to access the licensed technology but face unnecessary barriers or financial hardship, due to cost.

Also, KEI has had to divert resources in order to counteract the NIH’s unlawful lack of transparency, frustrating KEI’s mission, which involves informing the public about the activities of government, particularly as regards administration of taxpayer-funded resources. As explained below, the NIH has withheld information about the license without any valid legal basis for doing so. KEI was thus forced to pursue that information from other avenues, such as requesting it from private entities who did not have an obligation to report the information to the public and did not respond to our inquiries.<sup>12</sup>

## C. ARGUMENT

Appellants appeal the NIH’s decision to proceed with the license for the following reasons:

1. The NIH did not conduct the analysis required by 35 U.S.C. § 209(a)(1) to conclude that an exclusive license was a reasonable and necessary incentive;
2. Assuming that the NIH can establish that an exclusive license was necessary in this case, the NIH has not properly analyzed whether the scope of rights is limited to that which is “reasonably necessary” to induce the investment required to bring the invention to practical application, as required by 35 U.S.C. § 209(a)(2);
3. The public’s right to evaluate and comment on a proposed license under 35 U.S.C. § 209(e) was undermined by the NIH’s unjustified lack of transparency, particularly concerning the identity of the prospective licensee and the extent of federal funding of the licensed inventions;

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<sup>12</sup> KEI requested information about the covered inventions directly from co-inventors, University of Minnesota scientists Branden Moriarity and R. Scott McIvor. Moriarity and McIvor never responded to KEI’s inquiries. Similarly, KEI requested information about Intima Bioscience directly from the company. KEI called a telephone number listed for the company and asked the person who answered the call for the names of Intima Bioscience’s principals. The person who responded refused to answer the question himself but promised to call back. As far as KEI is aware, the company never followed up with the requested information.

4. The NIH did not request the advice of the Attorney General regarding whether the license would create or maintain a violation of federal antitrust laws; and
5. The NIH has not done anything to implement to objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

This appeal addresses each issue in turn.

1. The NIH lacks authority to execute the license because it did not conduct the analysis required by 35 U.S.C. § 209(a)(1) to conclude that an exclusive license was a reasonable and necessary incentive.

A federal agency may not license federally-owned technology on an exclusive basis without first determining that “(1) granting the license is a reasonable and necessary incentive to— (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public[.]” 35 U.S.C. § 209 (a)(1).

The NIH has failed to conduct the analysis required by 35 U.S.C. § 209 (a)(1) and thus lacks the authority to execute the proposed license.

During the comment period, KEI asked Dr. Burke why the NIH was proposing to grant an exclusive license in the subject technologies to Intima Bioscience. He responded: “Because NIH wishes to grant an exclusive license to improve the chances that the technology will be made available to the public.”

In its final response letter, the NIH’s discussion of exclusivity was limited to the following:

Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government’s intellectual property in the specified field of use.

The NIH’s analysis of exclusivity with respect to the proposed license thus consisted of the following two considerations:

- Whether an exclusive license would improve the chances that the technology will be made available to the public; and
- Whether the license applicant was qualified, technically and financially, to be granted the license.

Neither consideration tracks the statutory standard, which asks whether exclusivity is both (1) reasonable and (2) necessary to incentivize a company to bring an invention to market.

We interpret the word “necessary” according to its plain meaning. Merriam-Webster defines “necessary” to mean “absolutely needed; required.”<sup>13</sup> In the context of 35 U.S.C. § 209(a)(1), the word “necessary” plainly means that an agency may license a federally-owned invention on an exclusive basis only if no qualified business would agree to undertake the investment needed to bring the technology to market absent exclusive rights. Stated otherwise, if even one qualified firm would agree to commercialize the technology on a non-exclusive or co-exclusive basis, then an exclusive license would not be authorized under Section 209(a)(1).

The NIH’s Office of Technology Transfer (OTT) has expressed the same understanding of the term “necessary.” In a 2006 presentation by the OTT, two of the stated criteria for granting an exclusive license were that “practical application of technology has not been achieved and **may not be achieved under a non-exclusive license**” and that exclusivity is “[r]equired to attract investment capital or to justify capital expenditures[.]”<sup>14</sup> Thus, at least at one point in time, the NIH understood that necessary means “required” and not merely “helpful.”

Aside from being inconsistent with Section 209(a)(1), neither standard supplied by the NIH with respect to the instant license is sufficient to protect the public’s investment in biomedical research, which, according to the same OTT document, is part of the agency’s mission.

Granting exclusive rights to a license applicant will always improve the chances that the technology will be made available to the public. It is no secret that for-profit businesses prefer exclusive rights; that is what allows them to maximize revenues by charging the public whatever price the market can bear. But that concept is precisely what makes patients particularly vulnerable to businesses’ profit-maximizing strategies in the context of life-saving cell or gene therapies, and is why it is imperative that the NIH thoughtfully administers the criteria located at 35 U.S.C. § 209 to protect the public’s investment in those technologies. If “improving the chances” were the relevant legal standard for granting an exclusive license – and it is not – the NIH would be free to grant a monopoly in a federally-owned invention 100 percent of the time, guaranteeing American taxpayers the worst possible deal. On the other hand, by granting an exclusive license only where doing so can truly be considered “necessary,” the NIH would be able to promote innovation without compromising access.

Asking whether a license applicant is financially qualified to commercialize a technology likewise misses the mark. There may be any number of businesses interested in licensing federally-owned technology that possess the qualifications to bring an invention to market. The question is whether the NIH can persuasively demonstrate that no qualified firm would be willing to undertake that investment on a non-exclusive or co-exclusive basis.

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<sup>13</sup> <https://www.merriam-webster.com/dictionary/necessary>.

<sup>14</sup> <http://www.pfc.org.in/workshop/page50-53.pdf> (emphasis added).



The NIH document, *Best Practices for the Licensing of Genomic Inventions*, recognizes the importance of granting non-exclusive licenses in genomic inventions, such as the subject technology, “whenever possible.”<sup>15</sup> It states, in pertinent part:

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.

The NIH cannot demonstrate that exclusivity was necessary in this instance because it failed to advertise the invention to the public as available for licensing.

Typically, a biotech firm interested in licensing NIH-owned technologies can discover what inventions are available for licensing through at least two avenues. First, firms can use the *Find Technologies* search engine at the OTT website to search NIH-owned inventions by “Keywords,” “NIH OTT Ref. No. (aka E. no.),” “Inventor Last Name,” and other fields.<sup>16</sup> Or, if they click on “Licensing Opportunity” under the “Licensing” tab on the OTT homepage, businesses can find a list of available technologies.<sup>17</sup> Second, interested parties can search NIH inventions available for licensing in the Federal Register. The Department of Health and Human Services recognizes that “publication of a notice that an invention is available for licensing serves to meet one of the requirements of 37 C.F.R. § 404.7 if an exclusive or partially exclusive license is ultimately granted.”<sup>18</sup> It is thus the policy of PHS that “all PHS inventions that are available for licensing and for which a patent application has been filed . . . will be described in a notice published in the *Federal Register*.”<sup>19</sup> Neither avenue would have disclosed the subject inventions as available for licensing, however.

KEI searched the “E. nos.” pertaining to the subject inventions (E-171-2018, E-173-2018, and E-174-2018) in the *Find Technologies* search engine. No results were returned. Likewise, a search for the subject inventions in the Federal Register returned no results.

Dr. Burke confirmed that the NIH did not post the inventions as available for licensing using either the *Find Technologies* search engine or posting on the Federal Register. KEI asked Dr. Burke: “Did the NIH previously post this technology in the Federal Register under ‘Government

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<sup>15</sup> *Best Practices for the Licensing of Genomic Inventions - Final Notice* (April 2005), available at <https://www.govinfo.gov/content/pkg/FR-2005-04-11/pdf/05-7247.pdf>.

<sup>16</sup> <https://www.ott.nih.gov/licensing/licensing-process>.

<sup>17</sup> <https://www.ott.nih.gov/opportunities>.

<sup>18</sup> United States Public Health Service Technology Transfer Manual, Chapter No. 302, *PHS Policy for Preparing and Submitting Notices Regarding Licensing of PHS Inventions to the Federal Register for Publication*, available at <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/302-Policy.pdf>.

<sup>19</sup> *Id.*

Inventions available for licensing' or on the NIH's OTT Website's 'Licensing Opportunities'?" He responded: "No." On September 12, 2019, KEI asked Dr. Burke why the NIH did not post the inventions as available for licensing. He did not respond.

Because the NIH has not, and cannot, demonstrate that exclusivity was a reasonable and necessary incentive under 35 U.S.C. § 209(a)(1), it lacks the authority to execute the license.

2. Assuming that the NIH could establish that an exclusive license was necessary in this case, the license violates 35 U.S.C. § 209(a)(2) because the NIH has not met its statutory responsibility to limit the scope of rights to that which is not broader than "reasonably necessary" to induce the investment required to bring the invention to practical application, including, in particular, the number of years of exclusivity.

Even if the NIH properly concluded that exclusivity was both reasonable and necessary, it still lacks the authority to execute the license because it has not properly analyzed whether "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public[.]" 35 U.S.C. § 209 (a)(2).

The scope of a license in federally-sponsored technology may vary along the following (non-exhaustive) list of parameters:

- The duration of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (*i.e.*, five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (*i.e.*, targeted diseases).<sup>20</sup>

The NIH's lack of transparency has made it difficult for Appellants to evaluate how the NIH applied the criteria located at 35 U.S.C. § 209(a)(2) regarding scope - if the NIH engaged in that analysis at all. During the comment period, KEI asked Dr. Burke how the NIH determined that the "scope of exclusivity [is] no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology[.]" He responded as follows:

[C]onsideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

The NIH's final response letter, too, failed to answer KEI's question about the scope of the license, although timeliness objections no longer applied by that point. With respect to the scope of the license, the letter stated only:

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<sup>20</sup> 37 C.F.R. § 404.5(b).

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.

At the outset, the NIH's conclusory statement that it has satisfied the relevant legal standard is unbecoming of a federal agency that receives 40 billion dollars of public funds each year to promote biomedical research and is entrusted with ensuring that the fruits of that investment are available to the public on reasonable terms.

More importantly, KEI's correspondence with Dr. Burke about the duration of the license reveals that the NIH has not engaged in the analysis mandated by 35 U.S.C. § 209(a)(2), because it concluded that the license fulfilled all of the relevant criteria, which include that the scope of the license is not broader than reasonably necessary, without first determining the period of exclusivity.

During the comment period, KEI asked Dr. Burke to "please state the duration of exclusivity" of the license. Dr. Burke stated that he could not answer that question because the period of exclusivity "had not yet been determined." It is unclear why the NIH could not contemplate the period of exclusivity before commencing the notice and comment period; the NIH disclosed the other aspects of the license's proposed scope—such as its fields of use and territorial reach—in the Federal Register notice.

After the comment period had closed and the NIH issued its final determination letter stating that all license criteria were satisfied, KEI again asked Dr. Burke to state the period of exclusivity for the license. He still would not answer, claiming that the duration of the license was yet to be determined and that he could not estimate when that determination would be made. It is thus clear that the NIH's analysis of the relevant criteria did not include consideration of the duration of the license.

The NIH may not arbitrarily exclude the duration of exclusivity from its purview when analyzing the appropriate scope of an exclusive patent license. 35 U.S.C. § 209(a)(2) conditions the grant of such a license on the federal agency first determining that its scope is not broader than reasonably necessary. It does not specify that the scope of a license is measured only by its territorial reach or field of use. Moreover, technology transfer regulations require that federal agencies ensure that the duration of a proposed license serves the public interest. 37 C.F.R. § 404.5 - Restrictions and conditions on all licenses granted under this part, states as follows:

Licenses shall contain such terms and conditions as the Federal agency determines are appropriate for the protection of the interests of the Federal Government and the public[.] The following terms and conditions apply to any license: (1) The duration of the license shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part. . . .

37 C.F.R. § 404.5(b)(1).

Duration of exclusivity is arguably the most important licensing parameter, in terms of the public interest, because it most directly impacts price and access by determining the length of time that the licensee can set whatever price the market can bear. This is a particularly sensitive concern where, as here, an invention is directed toward treatment of life-threatening diseases, such as cancer and the demand for a life-extending therapy is especially inelastic.

Because the NIH failed to consider the duration of exclusivity when analyzing 35 U.S.C. § 209(a)(2), it lacks the authority to execute the proposed license.

3. The NIH has withheld relevant, non-confidential information about the license from the public, impeding the public's right to comment under 35 U.S.C. § 209 (e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely submitted comments. 35 U.S.C. § 209(e).

In order for the public to meaningfully participate in the notice-and-comment process, it must have basic information about the license.

The NIH has refused to answer questions seeking the following information, which relates directly to the criteria listed in Section 209 and is not "confidential business information":

- The amount of federal funding that has supported the licensed inventions;
- The identifying numbers of any NIH grants that are associated with the technology;
- The identity of any officers/directors of the prospective licensee, Intima Bioscience; and
- The period of exclusivity of the license.

Following is a discussion of how Dr. Burke refused to respond to KEI's requests for the information listed above, and why his objections lacked any legitimate legal or factual basis.

#### Federal Funding

Dr. Burke refused to disclose how much federal funding has supported the licensed inventions, to list which NIH grant numbers financed the inventions, or even to confirm whether a particular grant supported the inventions. Instead, he referred KEI to the inventors of the technology. KEI reached out to Moriarity and McIvor to inquire about funding. They never responded.

Also, in declining to answer KEI's questions about funding, Dr. Burke referred KEI to the NIH's RePORTER database.



While Appellants believe that recipients of government funds to conduct biomedical R&D should disclose information about such funding to the public, we see no valid reason why the NIH itself, as the administrator of the public funds, may refuse to state how much taxpayer funding contributed to a government-owned invention. There is no legitimate private interest involved that would preclude the NIH from providing that information to the public. If the NIH were fulfilling its duty to act as a responsible steward of the public's investment in biomedical research, it would be able to state the amount of public funding attributable to a particular invention.

Also, it is inaccurate to state that KEI can access the requested information using RePORTER. According to the NIH, "RePORTER . . . is an electronic tool that allows users to search a repository of both intramural and extramural NIH-funded research projects from the past 25 years and access publications (since 1985) and patents resulting from NIH funding."<sup>21</sup> Although RePORTER can provide a useful research tool, it did not enable KEI to determine the amount of federal funds that supported the subject inventions.

Many of the relevant patent documents contain the following government interest statement:

This invention was made with government support under project numbers Z01BC010985 and Z01BC010763 awarded by the National Institutes of Health, National Cancer Institute. The government has certain rights in the invention.<sup>22</sup>

Searching those grant numbers using RePORTER, KEI was unable to identify the portion of those grants that supported the invention. According to RePORTER, BC010985, titled "Gene Therapy of Cancer," is an intramural research grant administered by the NCI that spans fiscal years 2008 - 2018 and has allocated a total of \$24,434,060 to cancer research. Because the patents claim a priority date of 2015 and the grant was in effect through 2018, it would be inaccurate to state that all \$25 million supported the inventions. Even if we could isolate only the grant years that contributed to the inventions, we could not eliminate the possibility that the award for that year encompassed multiple studies. RePORTER does not isolate the funds that led to discovery of only the relevant inventions. Likewise, BC010763, "Building on the Success of the Adoptive Immunotherapy of Cancer," is an NCI grant project spanning 13 fiscal years and \$55,194,006 in total federal funding. As is the case with BC010985, it is impossible to determine which portion of the \$55 million supported only the discovery of the licensed technology. We also note that neither grant number links to the relevant patents/patent applications in RePORTER.

Finally, because neither Moriarity nor McIvor responded to KEI's inquiries, we could not determine whether any extramural grants to the University of Minnesota contributed to development of the technologies.

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<sup>21</sup> <https://report.nih.gov/brochure/index.html>.

<sup>22</sup> See U.S. patent 10,166,255 and U.S. patent applications 16/180867, 16/182146, 16/182189, and 16/182189.



### The Identities of Officers of Intima Bioscience, the Prospective Licensee

The NIH has also been non-transparent about the identity of the licensee, preventing the public from evaluating whether Intima Bioscience is qualified to commercialize the patented inventions.

As noted, Intima Bioscience is not registered to conduct business in New York, the state in which it is headquartered, and it maintains no website. Given the significance of the license to public health outcomes, the identity of the licensee that will likely hold a 20+ year monopoly on the subject technology is a compelling concern. It is not encouraging that Intima Bioscience has never issued a press release, does not maintain an online or social media presence, does not appear to ever have successfully brought an invention to market, and apparently is operating illegally in New York without a license to conduct business there.<sup>23</sup>

As noted above, the one-page website for related entity, Intima Capital, reinforces Appellants' concerns about the NIH granting a 20+ year monopoly in life-saving cancer treatments to the company. As our comments note, Intima Capital's website announces an investment strategy that is "predicated on the understanding that healthcare is an investible sector that is fundamentally non-discretionary [and uniquely inefficient]" and describes the company as being focused on "opportunistic private equity investments."<sup>24</sup>

Because KEI was able to learn virtually nothing about the company from internet search engines, it asked Dr. Burke to identify Intima Bioscience's principals/officers.

Dr. Burke refused to answer the question, stating that it was "confidential business information." When asked to identify some authority for that proposition, he cited 37 C.F.R. § 404.14.

The NIH's interpretation of 37 C.F.R. § 404.14 as precluding it from releasing the identity of a license applicant is not sound. 37 C.F.R. § 404.14 refers to "any **plan** submitted pursuant to § 404.8(h)[.]" 37 C.F.R. § 404.14(emphasis added). 37 C.F.R. § 404.8(h) lists 11 different components of a license application, of which only one, 37 C.F.R. § 404.8(a)(8), is a "plan." The other components, listed at 37 C.F.R. § 404.8(a)(1)-(7) and (9)-(11), are not "plans" and thus are not confidential. Since KEI did not ask Dr. Burke to disclose Intima Bioscience's development plan, 37 C.F.R. § 404.14 offered no basis for withholding the requested information.

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<sup>23</sup> For-profit corporations incorporated outside of New York may not conduct business in the state without first receiving authorization to do so. N.Y. Bus. Corp. Law § 1301(a). Intima Bioscience, Inc. is a foreign corporation because it was incorporated in Delaware. It is conducting business in NY, and is not registered with the NY Division of Corporations.

<sup>24</sup> <https://web.archive.org/web/20190912202840/http://intimacapital.com/>.

### Duration of the License

Lastly, and most importantly, Dr. Burke refused to disclose the duration of the license. Aside from stating that the period of exclusivity was yet to be determined, Dr. Burke also objected to disclosing the duration of the license on the basis that it was confidential business information. Appellants are not aware of any federal statute or regulation that makes the term of exclusivity for a license in a federally-owned invention “confidential business information.” 37 C.F.R. § 404.14 refers to license applicants’ development plans and licensee’s periodic utilization reports. Similarly, 35 U.S.C. § 209 refers only to commercial development plans and utilization reports as confidential. 35 U.S.C. §§ 209(d)(2)&(f).

Appellants are dismayed by the NIH’s habitual resort to citing inapplicable confidentiality provisions as a means to withhold information germane to its licensing decisions from the public. With no statute on point, the licensee’s identity and the duration of the license are confidential only if the private interest in nondisclosure outweighs the public’s interest in disclosure.<sup>25</sup> When a federal agency expends millions of taxpayers’ dollars to develop a life-saving technology, a strong case can be made that the public’s interest in knowing the identity of the company that intends to claim a monopoly on that invention outweighs the licensee’s interest (if there is one)<sup>26</sup> in shielding the identity of its officers from the public. Moreover, Appellants strongly question the notion that disclosure of the duration of an exclusive patent license might seriously harm the licensee’s business interests, threatening the success of NIH’s technology transfer program. Publicly-traded companies like Kite Pharma, the business that launched the commercially successful Yescarta, frequently disclose such terms in their SEC filings.<sup>27</sup>

### 3. As far as Appellants can determine, the NIH did not request the advice of the DOJ regarding whether the license would create or maintain a violation of federal antitrust laws.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property,” with

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<sup>25</sup> See *Pub. Citizen Health Research Grp. v. Nat’l Institutes of Health*, 209 F. Supp. 2d 37, 45 (D.D.C. 2002)(balancing the public interest in disclosure against the private interest in withholding the information when analyzing whether terms of an NIH patent license are exempt as confidential business information under Freedom of Information Act Exemption 4).

<sup>26</sup> We question how Intima Bioscience can raise the capital necessary to bring the covered inventions to market without establishing more of an internet or social media presence and publicizing its business endeavors to investors.

<sup>27</sup> See, e.g., [https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q\\_20150930.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q_20150930.htm).

certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term “property” in Section 559 includes intellectual property rights such as patents.

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked Dr. Burke whether it requested the advice of the U.S. Attorney General concerning the license. Dr. Burke did not answer.

On February 13, 2018, KEI emailed Dr. Lambertson and Karen Rogers, Acting Director of the NIH Office of Technology Transfer, asking whether NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests, as required by Section 559.

Ms. Rogers responded as follows:

The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.

The NIH’s statement about the applicability of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws

that include licensing amongst dispositions, either explicitly or by implication.

Finally, by granting a fully-exclusive license in a federally-owned invention for life of patent, and allowing termination of the license only in narrow, vaguely-defined circumstances, the NIH is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

4. The NIH has not implemented objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

The PHS's licensing policy is governed by the following principle, among others:

"PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."<sup>28</sup>

We object to any license that does not satisfy PHS's governing licensing principle of promoting access in developing countries.

It would be quite simple to at least ask the licensee to provide a plan, made public so there is some accountability, as to how access will be extended to countries with per capita incomes less than 30 percent of the United States. Not even making this part of the negotiation is appalling and inconsistent with PHS's own stated licensing policies.

#### **D. CONCLUSION**

For all of the reasons stated above, Appellants request that the NIH reverse its decision to proceed with the license at issue and reopen the license to competitive bidding. Any license in the subject inventions may not be executed unless the NIH can demonstrate that it engaged in the necessary analysis. The license agreement should incorporate the public interest safeguards referred to in our submitted comments, and before executing the license, the NIH must seek and obtain the antitrust advice of the U.S. Attorney General, who confirms that the license will not create or maintain a situation inconsistent with federal antitrust laws.

We request a hearing on this appeal.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment  
Public Citizen  
Social Security Works

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<sup>28</sup> PHS, *United States Public Health Service Technology Transfer Manual*, Chapter No. 300, PHS Licensing Policy, available at <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300-policy.pdf>.

LWC Health  
Ruth Lopert  
Manon Ress  
Terry Love

Attachments

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**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 9/13/2019 5:08:22 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]  
**Subject:** FW: Administrative Appeal, NIH Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272  
**Attachments:** Administrative Appeal, NIH Licenses to Kite in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20.pdf; Attachment A.pdf; Attachment B.pdf; Attachment C.pdf; Attachment D.pdf; Attachment E.pdf; Attachment F.pdf; Attachment G.pdf; Attachment H.pdf; Attachment I.pdf; Attachment J.pdf

Good Afternoon Mark – Could you please advise how this Administrative Appeal should be addressed? Please note that Dr. Collins has been copied. Regards, Karen

Karen Rogers  
Acting Director  
Senior Royalties Administrator  
Office of Technology Transfer  
6011 Executive Blvd, Suite 325  
Rockville, MD 20852  
Phone: 301-435-4359

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, September 13, 2019 12:42 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Cc:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>  
**Subject:** Administrative Appeal, NIH Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272

Dear Ms. Rogers:

The attached documents represent the administrative appeal and associated attachments submitted today by Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Universities Allied for Essential Medicines (UAEM), Social Security Works (SSW), and Clare Love, and titled "Appeal, Exclusive Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., a Wholly-Owned Subsidiary of Gilead Sciences, as Described in Federal Register Notices 84 FR 33270 and 84 FR 33272."

Thank you in advance for processing our appeal.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009

REL0000025144.0001

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 9/16/2019 1:16:44 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: [REDACTED] License Application Reference No. [REDACTED] 1.14.16.pdf  
**Attachments:** RE: Administrative Appeal, NIH Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272

Thanks for your guidance. Please see attached. Karen

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, September 16, 2019 9:14 AM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Cc:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** Re: [REDACTED] License Application Reference No. [REDACTED] 1.14.16.pdf

Just send as is. Dale is reviewing the issue and will determine how we will proceed. Thx

Sent from my iPhone

On Sep 16, 2019, at 8:54 AM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

Morning Mark and Dale – I have the e-mail ready to send back to KEL [REDACTED]  
[REDACTED] Do you think I should add  
another sentence? Thanks, Karen

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, September 13, 2019 5:03 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Subject:** RE: [REDACTED] License Application Reference No. [REDACTED] 1.14.16.pdf

Dale and I agree you should [REDACTED]

**b5**



**b5**

**From:** Rogers, Karen (NIH/OD) [E] <[rogersk@od.nih.gov](mailto:rogersk@od.nih.gov)>

**Sent:** Friday, September 13, 2019 3:56 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Subject:** **b4** License Application Reference No: **b4** 1.14.16.pdf

Hi Mark – I found a lot of information related to **b4** but this is the only document I could find that you could use as a reference to reply to KEI. Hope it helps. Karen

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**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 9/16/2019 1:15:37 PM  
**To:** kathryn ardizzone [kathryn.ardizzone@keionline.org]  
**CC:** Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]  
**Subject:** RE: Administrative Appeal, NIH Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272

Knowledge Ecology International  
Social Security Watch  
Universities Allied for Essential Medicine  
Union for Affordable Cancer Treatment  
Clare Love

RE: Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272

Dear Ms. Ardizzone:

Thank you for your letter of September 13, 2019 requesting that NIH reverse its decision to proceed with the license that was proposed in the Federal Register announcements referenced above.

Sincerely,

Karen Rogers  
Acting Director  
Senior Royalties Administrator  
Office of Technology Transfer  
6011 Executive Blvd, Suite 325  
Rockville, MD 20852  
Phone: 301-435-4359

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Friday, September 13, 2019 12:42 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Cc:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>  
**Subject:** Administrative Appeal, NIH Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., 84 FR 33270 and 84 FR 33272

Dear Ms. Rogers:

The attached documents represent the administrative appeal and associated attachments submitted today by Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Universities Allied for Essential Medicines (UAEM), Social Security Works (SSW), and Clare Love, and titled "Appeal, Exclusive Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., a Wholly-Owned Subsidiary of Gilead Sciences, as Described in Federal Register Notices 84 FR 33270 and 84 FR 33272."

Thank you in advance for processing our appeal.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

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**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 10/22/2019 12:16:13 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Fenn, Tedd (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0f88c66575c49fb9f70456838521059-fennea]  
**Subject:** RE: KEI Comments to NIH re: Exclusive License to Opsi Therapeutics  
**Attachments:** NIHtoKEI re MTTI 28Aug2019.docx

Tedd—this is proforma letter that I usually sent to KEI.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, October 21, 2019 05:58 PM  
**To:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** RE: KEI Comments to NIH re: Exclusive License to Opsi Therapeutics

Tedd:

Please prepare the standard acknowledgement letter

b5

b5

I really want to

b5

Thanks,  
Mark

**From:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>  
**Sent:** Saturday, October 19, 2019 8:37 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** FW: KEI Comments to NIH re: Exclusive License to Opsi Therapeutics

Hi Mark, Misha,  
Per usual KEI sent objections.  
-Tedd

**From:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Sent:** Friday, October 18, 2019 3:49 PM  
**To:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>  
**Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>  
**Subject:** RE: KEI Comments to NIH re: Exclusive License to Opsi Therapeutics

Yes

**From:** Fenn, Tedd (NIH/NCI) [E] <tedd.fenn@nih.gov>  
**Sent:** Friday, October 18, 2019 3:01 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>

**Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <[sabarni.chatterjee@nih.gov](mailto:sabarni.chatterjee@nih.gov)>

**Subject:** FW: KEI Comments to NIH re: Exclusive License to Opsis Therapeutics

Hi Richard,

This came in from KEI. Should I forward to Mark R., & Misha?

-T

**From:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

**Sent:** Friday, October 18, 2019 2:18 PM

**To:** Fenn, Tedd (NIH/NCI) [E] <[tedd.fenn@nih.gov](mailto:tedd.fenn@nih.gov)>

**Cc:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>; James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** KEI Comments to NIH re: Exclusive License to Opsis Therapeutics

Dear Mr. Fenn:

Attached, please find Knowledge Ecology International's comments regarding the "Prospective Grant of an Exclusive Patent License: Compositions, Devices and Processes for Production and Delivery of Cell Grafts of Manufactured Retinal Pigment Epithelium Cell(s) Alone, or in Combination With Photoreceptor Cells, and on a Biodegradable Support Scaffold Transplanted Subretinally for Intra-Ocular Ophthalmic Treatment of Conditions of Degeneration, Dysfunction or Terminal Injury of Retinal Pigment Epithelium and/or Photoreceptors in Humans" as described in Federal Register Notice 84 FR 52889.

Thank you in advance for processing our comments. We look forward to receiving the NIH's response.

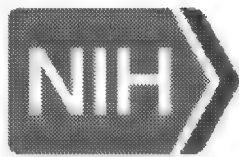
Sincerely,

Claire Cassedy

--

Claire Cassedy  
Knowledge Ecology International  
1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
Tel.: 1.202.332.2670

REL0000025147



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
Michael Shmilovich, Esq, CLP  
shmilovm@mail.nih.gov

August 28, 2019

James Packard Love  
Luis Gil Abinader  
Dr. Manon Anne Ress

IN RE: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that overexpress Integrin  $\alpha v \beta 3$   
84 FR 39001 (to Molecular Targeting Technologies, Inc. (MTTI)).

Dear Messrs. Love, Abinader and Dr. Ress:

Thank you for providing us with your comments regarding the aforementioned Federal Register notice. Prior to posting notices of the proposed grant of an exclusive commercial patent licenses, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) are satisfied and that the company applying for the license is qualified both technically and financially to take on the development of a product in the proposed field within the scope of the rights owned and licensed by the United States Government. We consider all comments prior to negotiating the proposed license and have considered your comments.

With regards to this license in particular, the scope of the license proposed is reasonable and necessary for incentivizing the company to undertake a difficult endeavor such as producing a radiotherapeutic of this kind on balance with the Government's interest in promoting the public health and public access to drugs.

We have read through and considered the terms and suggestions proffered in your bolded headings. If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>.

Sincerely,

**b6**

Michael A. Shmilovich, Esq., CLP

REL0000025147.0001

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**From:** Lampe, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3DDCC39C7E44ACA2125C44ESB51111-LAMPEKE]  
**Sent:** 6/15/2020 9:54:44 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: another KEI grant request  
**Attachments:** 5U01AR060911-02-Mendell.pdf; 5U01AR060911-03-Mendell.pdf; FOIA Response\_Letter. 05.04.20.pdf; 1U01AR060911-01A1-Mendell.pdf

Hi Mark,

There are 3 files with proposed redaction attached. They've been done in our FOIA software (separate from Adobe) so you won't be able to move the boxes around at all. If you have comments or see anything that needs changing you can write notes in Adobe and I will go into our software and make the changes. I've also attached the PI's response letter to the PDN but have not attached their redacted files. Let me know if you would like to see that also and I'll send it right along.

Thanks for looking at the files and let me know if you have any questions.

Karen

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, June 15, 2020 1:48 PM  
**To:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Subject:** RE: another KEI grant request

Great. Yes I would. Thanks

---

**From:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Sent:** Monday, June 15, 2020 2:42 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: another KEI grant request

Hi Mark,

Good questions. They are not the same, but no records were located for the R44. A PDN was done for the U01, the PI consulted the company and the company's suggested redactions were made. They have asked for a final look at the redactions before it goes out so I will do that once we get the ok from you. If you would like to look at the records themselves, I can send them to you. They're a fairly short 124 pages.

Thanks,  
Karen

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, June 15, 2020 1:00 PM  
**To:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Subject:** RE: another KEI grant request

Are the U01 and the SBIR R44 the same grant? Since it is a business grant, the business should review for confidential business information.

**From:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Sent:** Monday, June 15, 2020 1:45 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** another KEI grant request

Hi Mark,

I've got one more KEI request for a grant application. Two requests were combined as they asked for the same grant in two iterations. Same conditions apply as below for the two NIAID grants. I've attached the request for you. Please let me know if you are ok with this going out.

Thank you,  
Karen

**From:** Lampe, Karen (NIH/OD) [E]  
**Sent:** Friday, June 12, 2020 3:47 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Subject:** RE: two KEI FOIA requests

Thanks Mark. Just to be clear, you are ok with NIAID releasing the grants, right?

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, June 12, 2020 2:43 PM  
**To:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Subject:** RE: two KEI FOIA requests

Thanks. Fine with me

**From:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Sent:** Friday, June 12, 2020 2:50 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** two KEI FOIA requests

Good afternoon Mark,

I'm attaching two KEI requests for your quick read. These requests are both for copies of NIAID grants investigating HIV. The IC has conducted PDNs for both and redacted as desired by the Pls. I have skimmed through the grants and don't see anything that might require you to look at them except **b5**

**b5** I've attached it to this email as well. Let me know if you would like to see copies of the grant proposals but be aware that they are over 500 pages each.

Let me know if you have any questions.

**Karen E. R. Lampe, Ph.D.**  
Government Information Specialist  
NIH Freedom of Information Office (HNA83)  
[karen.lampe@nih.gov](mailto:karen.lampe@nih.gov)



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**From:** Lampe, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3DDCC39C7E44ACA2125C44ESB51111-LAMPEKE]  
**Sent:** 6/15/2020 5:44:44 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** another KEI grant request  
**Attachments:** FOIA request 53757.pdf; PAL Request Form.pdf

Hi Mark,

I've got one more KEI request for a grant application. Two requests were combined as they asked for the same grant in two iterations. Same conditions apply as below for the two NIAID grants. I've attached the request for you. Please let me know if you are ok with this going out.

Thank you,  
Karen

**From:** Lampe, Karen (NIH/OD) [E]  
**Sent:** Friday, June 12, 2020 3:47 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Subject:** RE: two KEI FOIA requests

Thanks Mark. Just to be clear, you are ok with NIAID releasing the grants, right?

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, June 12, 2020 2:43 PM  
**To:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Subject:** RE: two KEI FOIA requests

Thanks. Fine with me

**From:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>  
**Sent:** Friday, June 12, 2020 2:50 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** two KEI FOIA requests

Good afternoon Mark,

I'm attaching two KEI requests for your quick read. These requests are both for copies of NIAID grants investigating HIV. The IC has conducted PDNs for both and redacted as desired by the PIs. I have skimmed through the grants and don't see anything that might require you to look at them except [REDACTED] b5

[REDACTED] b5 [REDACTED] I've attached it to this email as well. Let me know if you would like to see copies of the grant proposals but be aware that they are over 500 pages each.

Let me know if you have any questions.

**Karen E. R. Lampe, Ph.D.**  
Government Information Specialist  
NIH Freedom of Information Office (HNA83)  
[karen.lampe@nih.gov](mailto:karen.lampe@nih.gov)

REL0000025150



Knowledge Ecology International  
1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
Tel.: 202.332.2670

National Institute of Arthritis and  
Musculoskeletal and Skin Diseases (NIAMS)  
FOIA Office  
6705 Rockledge Dr.  
Bethesda, MD 20817

Via Email: [nhlbifoiarequest@nhlbi.nih.gov](mailto:nhlbifoiarequest@nhlbi.nih.gov)

March 13, 2020

Dear FOIA Officer,

Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests copies of all records relating to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) grant U01AR060911. This request includes, but is not limited to, the grant application, the budget and its annexes, the NCI grant award notice, the grant itself, and all of the progress reports submitted by the grant recipient.

The period of this request is from January 1, 2009, to the present.

#### **Request for Full Waiver of Fees**

KEI requests that the processing fee be waived. This request will likely contribute significantly to the public understanding of the federal government's contribution to the discovery and development of health technologies.

KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *the Financial Times* and in several academic and policy journals.

The stories listed in Annex 1 demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. See *Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

### **Additional Comments**

Please provide the documents requested in electronic format.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to [kei-foia-request@keionline.org](mailto:kei-foia-request@keionline.org).

Thank you in advance for your assistance.

Sincerely,

Luis Gil Abinader  
Knowledge Ecology International  
[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)

### **ANNEX 1**

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested

records to the public. KEI operates websites including keionline.org and drugdatabase.info that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as ip-health, which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at keionline.org.

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests in the open source database drugdatabase.info:

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/nih-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "[U.S. nixed India's plea on reforms in medicine](#)," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. [Front page](#).

- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," *Inside Views, IP-Watch.Org*.



## Submit New Request

### Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

#### Luis Gil Abinader

Knowledge Ecology International (KEI)

1621 Connecticut Avenue NW

#500

Washington, DC 20009

Phone 202-332-2670

luisgilabinader@gmail.com

Requester Default Category: Educational/Non-Commercial/Scientific

### General Information

Institute or Center	NIAMS
Institute or Center Name	NIAMS
Request Type	FOIA
Requester Category	Educational/Non-Commercial/Scientific

### Shipping Address

State (Other)

### Request Information

Description Document	NIH NIAMS grant R44AR046154 FOIA request.pdf
Description	Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests copies of all records relating to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) grant R44AR046154. This requests includes, but is not limited to, the grant application, the budget and its annexes, the NCI grant award notice, the grant itself, and all of the progress reports submitted by the grant recipient.
Date Range for Record Search:From	01/01/1998
Date Range for Record Search:To	01/01/2020

### Fee Information

Willing to Pay All Fees	Yes
Willing Amount	\$25
Fee Waiver Requested	Yes ,NIH NIAMS grant R44AR046154 FOIA request.pdf
Fee Waiver Request Reason	KEI requests that the processing fee be waived. This request will likely contribute significantly to the public understanding of the federal government's contribution to the discovery and development of health technologies.

### Billing Address

State (Other)

### Other Information

State (Other)

### Expedite Information

Expedite Requested	No
Expedite Reason	

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 6/15/2020 1:18:47 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Mark:

I think

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**b5**

Let me know if you want to discuss.

Best, Dale

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, June 12, 2020 2:39 PM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** FW: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Dale:

These type of questions and objections come from KEI about every other week. I have asked her to

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But my point is

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TGIF

Thanks

Mark

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, June 12, 2020 2:00 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** Fwd: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

REL0000025151

Sent from my iPhone

Begin forwarded message:

**From:** "Choudhry, Vidita (NIH/NHLBI) [E]" <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Date:** June 12, 2020 at 1:46:35 PM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** "Goldstein, Bruce (NIH/NHLBI) [E]" <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** FW: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Just wanted to touch base to see if you need additional information or have any questions on our response to KEI's comments.

Best regards,

Vidita

**From:** Choudhry, Vidita (NIH/NHLBI) [E]  
**Sent:** Thursday, June 11, 2020 8:46 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Good Morning Mark,

Attached is the comment letter from KEI that was received after FRN close date/time.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Wednesday, June 10, 2020 5:31 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Sent:** Wednesday, June 10, 2020 5:11 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

REL0000025151

**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Attached please find a response letter that I plan to send to KEI. Please review and let me know if there are any concerns.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Sent:** Tuesday, June 9, 2020 10:18 AM

**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

**Subject:** Re: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

Sent from my iPhone

On Jun 9, 2020, at 8:29 AM, Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)> wrote:

Hi Mark,

What do you think of the text below?

Regards,

**Bruce Goldstein, Esq., Director**

NHLBI Office of Technology Transfer & Development

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

**Sent:** Monday, June 8, 2020 4:51 PM

**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

**Subject:** FW: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**

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2. How much did the NIH spend to develop the patented invention?

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3. What grants are associated with the patented invention?

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4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?

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5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?

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6. How has/will the NIH ensured that the scope of the license is not broader than necessary?

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7. What is the proposed duration of the license?

b5

Best regards,

Vidita

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Thursday, June 4, 2020 9:51 AM

**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Dear Dr. Choudhry:

Please answer the following questions (which have never been previously asked and are relevant to the statutory criteria under 35 U.S.C. 209) regarding the Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas (<https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>).

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**
2. How much did the NIH spend to develop the patented invention?
3. What grants are associated with the patented invention?
4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?
5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?
6. How has/will the NIH ensured that the scope of the license is not broader than necessary?
7. What is the proposed duration of the license?

Thank you in advance for your cooperation.

REL0000025151

Sincerely,

--

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]  
**Sent:** 4/9/2020 1:09:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Maples, Ronald (NIH/OD/ORS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c131fbce8654135af95151c728ebbbd-maplesre]; Partin, Kathryn (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb8f9dc1b4064c40af395b7551852d6c-partinkm]  
**Subject:** RE: Patent Information  
**Attachments:** b5,b6,b7(A)

Hi Mark – Reports and documents attached. b5,b7(A) The license garnered the attention of KEI. Let me know if I can pull any additional information. Regards, Karen

Karen Rogers  
Acting Director  
Senior Royalties Administrator  
Office of Technology Transfer  
6011 Executive Blvd, Suite 325  
Rockville, MD 20852  
Phone: 301-435-4359

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, April 8, 2020 5:01 PM  
**To:** Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>  
**Subject:** FW: Patent Information

Karen:

I don't have access to TTS from home. Could you please b5,b7(A)  
b5,b6,b7(A)

If there is something, please send the list back in a file to me.

Stay healthy  
Mark

**From:** Partin, Kathryn (NIH/OD) [E] <kathryn.partin@nih.gov>  
**Sent:** Wednesday, April 8, 2020 4:35 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: Patent Information

Hi Mark,  
Do you have any time to take a look at b5,b6,b7(A) Please see the attached, which Ron is wondering about.

Hope you are doing well!

Thanks!  
Kathy

**From:** Maples, Ronald (NIH/OD/ORS) [E] <[ronald.maples@nih.gov](mailto:ronald.maples@nih.gov)>  
**Sent:** Wednesday, April 8, 2020 4:06 PM  
**To:** Partin, Kathryn (NIH/OD) [E] <[kathryn.partin@nih.gov](mailto:kathryn.partin@nih.gov)>  
**Subject:** Patent Information

Hi Kathy,

I was doing some research on patents and came across this one that peaked my interest. b5,b7(A)

**b5,b7(A)**

Thanks,

**b6**

Office of Security and Emergency Response  
National Institutes of Health

(office)  
(mobile)

**b6**



**National Institutes of Health**  
*Turning Discovery Into Health*

NOTE: This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED, PRIVILEGED, and/or CONTROLLED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you have received this communication in error, please erase all copies of the message and its attachments and notify me immediately.

REL0000025152

**b5,b6,b7(A)**

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**b4,b5,b6,b7(A)**

**b4,b5,b6,b7(A)**

**b4,b5,b6,b7(A)**

**b5,b6,b7(A)**

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**From:** Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]  
**Sent:** 6/15/2020 2:44:18 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Questions, 85 FR 28966

Hi Mark,

I have a FRN that is expiring tomorrow June 15.

Aside from [REDACTED] b5  
[REDACTED] b5  
Is it [REDACTED] b5

Thanks,  
Jim

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Thursday, June 11, 2020 9:44 AM  
**To:** Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>; James Love <james.love@keionline.org>  
**Subject:** Questions, 85 FR 28966

Dear Dr. Knabb:

As soon as practicable, please answer the following questions regarding the two proposed exclusive patent licenses described in the Federal Register at 85 FR 28966 (to Vor Pharma and Senti Bio), which both cover Invention No. E-097-2018-0.

1. Is the invention being investigated in any clinical trials? What about this trial: [NCT03971799](#), Study of Anti-CD33 Chimeric Antigen Receptor-Expressing T Cells (CD33CART) in Children and Young Adults With Relapsed/Refractory Acute Myeloid Leukemia? (Sponsored by NIH and CHOP).
2. How much has the NIH/NCI spent to develop the invention? What grant numbers are associated with it?
3. What is the duration of the licenses? Life of patent? (If you haven't negotiated it yet, but you know that it will be life of patent because that's a model term and NIH tech transfer officers always grant life of patent, please let us know).
4. Have you narrowed the scope of the license in any way other than field of use?
5. How did you determine that exclusivity is a necessary incentive? What did your analysis consist of?
6. How did you determine that the scope of exclusivity is not broader than the necessary incentive? What did your analysis consist of?

Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)



(202) 332-2670

---

**From:** Choudhry, Vidita (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=68DF40CC95AE4FE9AA5851374EF0CA07-CHOUDHRYV2]  
**Sent:** 6/12/2020 6:40:17 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Thank you for your feedback, I will incorporate your suggestions in the response letter.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, June 12, 2020 2:29 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** FW: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Vidita:

Thanks. A few comments. [REDACTED] b5 [REDACTED] It would be helpful to [REDACTED] b5 [REDACTED]  
[REDACTED] b5 [REDACTED] The idea is to [REDACTED] b5 [REDACTED]  
[REDACTED] b5 [REDACTED]  
[REDACTED] b5 [REDACTED] Unless you have a better idea.

-Mark

Begin forwarded message:

**From:** "Choudhry, Vidita (NIH/NHLBI) [E]" <vidita.choudhry@nih.gov>  
**Date:** June 12, 2020 at 1:46:35 PM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Cc:** "Goldstein, Bruce (NIH/NHLBI) [E]" <goldsteb@mail.nih.gov>  
**Subject:** FW: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Just wanted to touch base to see if you need additional information or have any questions on our response to KEI's comments.

Best regards,

Vidita

---

**From:** Choudhry, Vidita (NIH/NHLBI) [E]  
**Sent:** Thursday, June 11, 2020 8:46 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Good Morning Mark,

Attached is the comment letter from KEI that was received after FRN close date/time.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Wednesday, June 10, 2020 5:31 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Sent:** Wednesday, June 10, 2020 5:11 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Attached please find a response letter that I plan to send to KEI. Please review and let me know if there are any concerns.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, June 9, 2020 10:18 AM  
**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>  
**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

REL0000025156

**Subject:** Re: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

Sent from my iPhone

On Jun 9, 2020, at 8:29 AM, Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)> wrote:

Hi Mark,

What do you think of the text below?

Regards,

**Bruce Goldstein, Esq., Director**

NHLBI Office of Technology Transfer & Development

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

**Sent:** Monday, June 8, 2020 4:51 PM

**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

**Subject:** FW: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**

**b5**

2. How much did the NIH spend to develop the patented invention?

**b5**

3. What grants are associated with the patented invention?

**b5**

4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?

**b5**

5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?

**b5**

6. How has/will the NIH ensured that the scope of the license is not broader than necessary?

**b5**

7. What is the proposed duration of the license?

**b5**

REL0000025156

Best regards,

Vidita

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>

**Sent:** Thursday, June 4, 2020 9:51 AM

**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>

**Cc:** James Love <james.love@keionline.org>

**Subject:** Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Dear Dr. Choudhry:

Please answer the following questions (which have never been previously asked and are relevant to the statutory criteria under 35 U.S.C. 209) regarding the Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

(<https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>).

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**
2. How much did the NIH spend to develop the patented invention?
3. What grants are associated with the patented invention?
4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?
5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?
6. How has/will the NIH ensured that the scope of the license is not broader than necessary?
7. What is the proposed duration of the license?

Thank you in advance for your cooperation.

Sincerely,

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]  
**Sent:** 6/12/2020 5:59:41 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Fwd: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas  
**Attachments:** KEI, UACT Comments, Proposed License to Retargeted Therapeutics (85 FR 31193).pdf; ATT00001.htm; NIH to KEI re FRN 85FR31193 10JUN2020.docx; ATT00002.htm

Sent from my iPhone

Begin forwarded message:

**From:** "Choudhry, Vidita (NIH/NHLBI) [E]" <vidita.choudhry@nih.gov>  
**Date:** June 12, 2020 at 1:46:35 PM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Cc:** "Goldstein, Bruce (NIH/NHLBI) [E]" <goldsteb@mail.nih.gov>  
**Subject:** FW: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Just wanted to touch base to see if you need additional information or have any questions on our response to KEI's comments.

Best regards,

Vidita

**From:** Choudhry, Vidita (NIH/NHLBI) [E]  
**Sent:** Thursday, June 11, 2020 8:46 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Good Morning Mark,

Attached is the comment letter from KEI that was received after FRN close date/time.

Best regards,

Vidita

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, June 10, 2020 5:31 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>

REL0000025158

**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

**Sent:** Wednesday, June 10, 2020 5:11 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Cc:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

**Subject:** RE: KEI Questions: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

Attached please find a response letter that I plan to send to KEI. Please review and let me know if there are any concerns.

Best regards,

Vidita

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**Sent:** Tuesday, June 9, 2020 10:18 AM

**To:** Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)>

**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>

**Subject:** Re: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**

Sent from my iPhone

On Jun 9, 2020, at 8:29 AM, Goldstein, Bruce (NIH/NHLBI) [E] <[goldsteb@mail.nih.gov](mailto:goldsteb@mail.nih.gov)> wrote:

Hi Mark,

What do you think of the text below?

Regards,

**Bruce Goldstein, Esq., Director**

NHLBI Office of Technology Transfer & Development

REL0000025158



**From:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Sent:** Monday, June 8, 2020 4:51 PM  
**To:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** FW: Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**

b5

2. How much did the NIH spend to develop the patented invention?

b5

3. What grants are associated with the patented invention?

b5

4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?

b5

5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?

b5

6. How has/will the NIH ensured that the scope of the license is not broader than necessary?

b5

7. What is the proposed duration of the license?

b5

Best regards,

Vidita

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Thursday, June 4, 2020 9:51 AM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Dear Dr. Choudhry:

Please answer the following questions (which have never been previously asked and are relevant to the statutory criteria under 35 U.S.C. 209) regarding the Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas (<https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>).

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**

2. How much did the NIH spend to develop the patented invention?

REL0000025158



3. What grants are associated with the patented invention?
4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?
5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?
6. How has/will the NIH ensured that the scope of the license is not broader than necessary?
7. What is the proposed duration of the license?

Thank you in advance for your cooperation.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

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Suite 500  
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June 8, 2020

Vidita Choudhry, Ph.D.  
Technology Transfer Manager  
31 Center Drive Room 4A29, MSC2479  
9609 Medical Center Drive  
Bethesda, MD 20892-2479  
Via Email: [vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)

**Re: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas, 85 FR 31193, to the firm, Retargeted Therapeutics**

Dear Dr. Choudry:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) are writing to comment on the "Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas" to "Retargeted Therapeutics, a corporation incorporated under the laws of the state of Delaware," as described in the Federal Register notice located at [85 FR 31193](#) ("the notice").<sup>1</sup>

The inventions were supported by funding from U.S. taxpayers, with the aim to make certain monoclonal antibody treatments more effective in combating B-cell lymphomas.

To grant the license, the National Institutes of Health (NIH) must determine that it serves the public interest, that exclusivity is necessary to incentivize a company to commercialize the invention, and that the scope of the license is not broader than necessary. The NIH must also seek the antitrust advice of the U.S. Attorney General before executing the license.

We are concerned that the process for the proposed license lacks transparency, and that the license will not serve the public interest.

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<sup>1</sup> 85 Fed. Reg. 31193 (May 22, 2020), available at <https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>.

According to the FR notice, Retargeted Therapeutics is incorporated in Delaware. But there is no evidence of such registration in the state's online business records. Even more puzzling, the company that the NIH has chosen for an exclusive license does maintain a website.

The NIH has not responded to several questions about the license.

Based upon the NIH's prior approach toward its technology transfer responsibilities under the Bayh-Dole Act and its other legal duties, we are concerned that the NIH has not engaged in the type of economic analysis required by 35 U.S.C. § 209(a), and it is our assumption that the NIH has failed to seek the advice of the U.S. Attorney General, as is required by statute.

It is especially difficult to comment on a license when the terms of the license are not disclosed by the NIH, and the company is a ghost.

## Background

### The Inventions

The proposed license covers seven patents or patent applications, all titled, "Antibody Targeting Cell Surface Deposited Complement Protein 3d and Use Thereof."<sup>2</sup>

The patent filing dates range from January 8, 2014 to December 9, 2019, roughly seven months ago.

Four of the patent applications are in the United States, including one that was granted on July 31, 2018, and three that are still pending. There is one patent application pending in Canada, one application to the WIPO PCT, and one application to the EPO, which was granted on September 18, 2019.

NIH ref No.	Title	Patent application No.	Filing date	Issue date	Issued patent No.
E-758-2013-0-US-01	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	61/924,967	Jan 8, 2014		
E-758-2013-1-PCT-01	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	PCT/US2015/010620	Jan 8, 2015		
E-758-2013-1-US-02	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	15/110,577	Jul 8, 2016	Jul 31, 2018	10,035,848
E-758-2013—1-CA-03	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	2936346	Jan 8, 2015		

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<sup>2</sup> *Id.*

E-758-2013-1-EP-04	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	15701442.4	Jan 8, 2015	Sep 18, 2019	3092252
E-758-2013-1-US-05	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	16/047,929	Jul 27, 2018		
E-025-2019-0-US-01	Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof	62/945,569	Dec 9, 2019		

U.S. Patent No. 10,035,848, (the “848 patent”) was issued on July 31, 2018. The inventors listed on the ‘848 patent are Adrian Wiestner, Martin Skarynski, Margaret Lindorfer, Ronald Taylor, Christoph Rader, and Berengere Vire.<sup>3</sup> According to the USPTO publication, the ‘848 patent is co-assigned to the University of Virginia Patent Foundation, but the notice fails to mention this or to explain the role of the University of Virginia Patent Foundation in the proposed license. The patent text contains the following statement of “Government Interests”:

This invention was made with Government support under project number 1ZIHL006070-03 by the National Institutes of Health, National Heart, Lung, and Blood Institute. The Government has certain rights in the invention.<sup>4</sup>

1ZIAHL006070-03 is a Fiscal Year 2012 intramural grant from the National Heart, Lung, and Blood Institute (NHLBI) for \$482,780. The principal investigator for the project is Dr. Adrian Wiestner.

The Federal Register notice disclosing the invention as available for licensing, 83 FR 51969, states that the technology was invented by researchers at NIH and the

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<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtml%2FPTO%2Fs&search-adv.htm&r=1&f=G&l=50&d=PTXT&p=1&S1=10,035,848&OS=10,035,848&RS=10,035,848>.

<sup>4</sup> *Id.*

University of Virginia School of Medicine.<sup>5</sup> It also states that the publication, “A CD19/CD3 bispecific antibody for effective immunotherapy of chronic lymphocytic leukemia in the ibrutinib era,”<sup>6</sup> is relevant to the invention. That article lists, as support, the intramural program at NHLBI and NIH Grant No. R01 CA181258, a grant to Christoph Rader from 2014 to 2018 for a total of \$1,985,775.

### Scope of the License

The proposed territorial reach of the license is worldwide, and the “fields of use that may be limited to use of anti-C3d monoclonal antibodies (mAbs) to potentiate anti-tumor activity of anti-CD20 mAbs for the treatment of B-cell lymphomas.”<sup>7</sup> The proposed fields of use appear to be commensurate with the claims in the ‘848 patent. The notice does not state the proposed term of exclusivity.

### The Prospective Licensee

The prospective licensee, Retargeted Therapeutics, does not maintain a website and is not incorporated in the state of Delaware, according to Delaware’s online business records. KEI searched the terms “Retargeted Therapeutics” and “Retargeted” in the “Entity Name” field at the Delaware Department of State: Division of Corporations website (<https://icis.corp.delaware.gov/ecorp/entitysearch/namesearch.aspx>), and no results were returned.

## **Discussion**

### 1. The prospective licensee, Retargeted Therapeutics, is a Ghost.

Retargeted Therapeutics is not listed in the Delaware Division of Corporations public database as a company incorporated in Delaware, and more importantly, does not have any public presence, and has no history of commercializing inventions.

In order to grant an exclusive patent license, the NIH must find, among other requirements, “that the public will be served by the granting of the license, as indicated by *the applicant’s intentions, plans, and ability to bring the invention to practical application* or otherwise promote the invention’s utilization by the public.” 35 U.S.C. § 209(a)(2)(emphasis added). Achieving “practical application” requires making an invention available to the public “*on reasonable terms.*” 35 U.S.C. § 201(f)(emphasis added).

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<sup>5</sup> 83 Fed. Reg. 51969 (Oct. 15, 2018), available at <https://www.govinfo.gov/content/pkg/FR-2018-10-15/pdf/2018-22359.pdf>.

<sup>6</sup> Robinson HR, Qi J, Cook EM, et al. A CD19/CD3 bispecific antibody for effective immunotherapy of chronic lymphocytic leukemia in the ibrutinib era. *Blood*. 2018;132(5):521-532. doi:10.1182/blood-2018-02-830992.

<sup>7</sup> 85 FR 31193.



The Federal Register Notice for the proposed license states that Retargeted Therapeutics is incorporated in Delaware. As noted above, KEI searched the online business records of Delaware, and no business of the name Retargeted Therapeutics or containing “Retargeted” is registered to conduct business or incorporated in Delaware. In addition, Retargeted Therapeutics does not maintain a website or any sort of social media presence. Because of the lack of any publicly available information about Retargeted Therapeutics, it is impossible to determine whether the company has the capacity to develop the invention into a product that is beneficial to cancer patients, let alone whether it will commit to making the technology available to the public on reasonable terms.

KEI emailed Dr. Vidita Choudry, the point of contact for the license, the question: “How can the public be assured that a non-registered, non-entity with no public presence and no history of commercializing inventions will use this invention in a way that is beneficial to the public?” She did not answer prior to 5 p.m. on the close of the comment period. KEI called Dr. Choudry at 3 p.m. on June 8, 2020, and asked her for the names of the principal officers of Retargeted Therapeutics. She would not answer, repeatedly stating that she would respond to KEI’s email “in due time,” even after KEI pointed out that the comment period would close that same day. KEI sent a follow-up email, asking for the identities of Retargeted’s principal officers, and explaining that the information is not available online. She did not respond prior to 5 p.m. on the close of the comment period. KEI also asked Dr. Wiestner, one of the inventors of the technology, for the names of the principal officers of Retargeted Therapeutics. He did not respond prior to 5 p.m. on the close of the comment period, either.

*2. We believe that NIH has not meaningfully evaluated whether the scope of exclusivity is not broader than necessary.*

The grant of a monopoly on a federally funded invention is subject to restrictions in the Bayh-Dole, and in particular, when the invention is owned or partly owned by the federal government.

We are concerned that the NIH likely has not properly considered the scope of rights in the exclusive license is not broader than necessary, for example, as regards the number of years of exclusivity.

Nonexclusive licenses are preferred.<sup>8</sup> The NIH may grant an exclusive or partially exclusive license only when “granting the license is a reasonable and necessary incentive to—call forth

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<sup>8</sup> PHS, *Policy for Making Determines Regarding the Grant of Exclusive or Partially Exclusive Commercialization*, United States Public Health Service Technology Transfer Policy Manual Chapter No. 305 (June 20, 2013), available at <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/305-policy.pdf>.

the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public[.]” 35 U.S.C. § 209(a)(1).

If the NIH determines that exclusivity is a necessary incentive, it must also ensure that the scope of the license is not broader than needed. See 35 U.S.C. § 209(a)(2) (requiring that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public[.]”).

KEI emailed Dr. Choudhry a list of questions about the license and the NIH's analysis. Among other questions, KEI asked how the NIH determined that exclusivity is a necessary incentive and that the scope of the license does not exceed the incentive needed. She did not respond prior to the close of the comment period.

Based on the NIH's previous statements regarding exclusive patent licenses, we can assume that it did not perform the analysis required by 35 U.S.C. § 209(a)(1)-(2). KEI has raised two main issues with respect to exclusivity and the scope of proposed licenses: whether the NIH performed any economic analysis of the necessity of exclusivity and whether it considered limiting the scope of exclusivity to shorter than life of patent. The NIH answered both questions in the negative in the past, stating that for early stage therapeutics there is no demand for non-exclusive licenses, and that more controversially, that companies will not commit to commercializing an invention unless they are granted exclusivity for life of patent.<sup>9</sup> We have also asked whether the NIH has considered limiting exclusivity to high-income countries, or to non-US markets, but have not received a response to that inquiry, even though there is ample evidence that companies develop therapies with exclusivity limited to only one country, or some countries. For example, it is not uncommon for a company to expect exclusivity only in the United States, or only in European markets, even when inventions were not subsidized by the federal government.

The NIH's across-the-board assumptions about the necessary incentive do not satisfy its obligations under the Bayh-Dole Act. As the NIH has recognized, every invention is different and has unique commercial value. 35 U.S.C. § 209(a) requires a case-specific analysis. Specifically, in order to conclude that an exclusive license is necessary and that the scope of the license is not broader than necessary, some analysis must be undertaken, including, for example, consideration of the other types of incentives provided by law, such as test data protection, Orphan Drug exclusivity, etc., and the likely case that the developer can bring other patented inventions into the project, for which exclusivity exists. The NIH must also consider the possibility that a license for shorter than life of patent will be adequate to incentivize a company to commercialize a federally-owned invention, as it has done with numerous products for the treatment of cancer, including cases where products were only protected by five years

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<sup>9</sup> Letter from Mark Rohrbaugh, Ph.D., J.D., NIH Special Advisor for Technology Transfer, to KEI (Nov. 26, 2019) (on file with KEI).

of exclusive rights in regulatory test data, with no patents. If the NIH did not investigate the possibility of granting a non exclusive or co-exclusive license, limiting the term of the proposed license, or otherwise limiting the terms, such as granting exclusivity only to non-US high income countries, it has not satisfied its obligations under 35 U.S.C. § 209(a)(1)-(2).

3. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

We object to the license because the NIH has not first obtained the antitrust advice of the United States Attorney General before disposing of government-owned property.

Under the Federal Property and Administrative Services Act, 40 U.S.C. § 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property.” The statute exempts personal property if the fair market value is less than \$3,000,000, but specifically excludes “a patent, process, technique, or invention” from that exception.

The regulation 41 C.F.R. § 102-75.270 also makes clear the inclusion of patents “irrespective of cost.”

KEI asked Dr. Choudry whether the NIH requested the advice of the U.S. Attorney General concerning the licenses. Dr. Choudry did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally governed by the Bayh-Dole Act and its regulations.

We disagree.

35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.



The term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants an exclusive license in a federally-owned invention, it is disposing of a government property interest so as to trigger 40 U.S.C. § 559.

4. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public’s interest in the NIH-funded technology:

1. **Geographic scope of exclusivity.** If the NIH decides to grant exclusive rights to the subject inventions, it should limit exclusivity to the European Union, Japan and other high-income countries, but not the United States, so that countries that did not fund the R&D underlying the inventions would bear the costs of the exclusivity, while the US residents would not. The NIH should also limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.
2. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
3. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”
4. **Global registration and affordability.** The license should require Retargeted Therapeutics to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by

supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

5. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
6. **Years of exclusivity.** We propose the license reduces the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]”
7. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

## Conclusion

We object to the proposed license to Retargeted Therapeutics for the reasons stated herein. In the event that the NIH grants the license, we ask that it incorporates the provisions listed above, which are designed to protect the public interest in the licensed technologies and to

accomplish the policies outlined in the PHS Technology Transfer Manual and Section 200 of the Bayh-Dole Act.

Sincerely,

Knowledge Ecology International  
Union for Affordable Cancer Treatment

**b5**

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**From:** Wong, Jennifer A (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6603ED16C184B8B83F02F5FA40A05DF-WONGJA]  
**Sent:** 6/9/2020 3:24:29 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Predescu, Alina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a60e98376e746c7a37640bd40f45149-predescuad]  
**Subject:** CRADA paper updated version 6/9/20  
**Attachments:** CRADA reasonable pricing clause discussion May 29 MLRrevised.docx

Hi, Mark.

I revised this. There are still questions throughout, but we can go over this in the meeting today if we have time after we discuss vision/thoughts on the TTIP website and other things that you'd like to cover.

Jennifer Wong, PhD  
AAAS Science and Technology Fellow  
Division of Technology Transfer & Innovation Policy  
Office of Science Policy, Office of the Director  
National Institutes of Health

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**From:** Choudhry, Vidita (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=68DF40CC95AE4FE9AA5851374EF0CA07-CHOUDHRYV2]  
**Sent:** 6/9/2020 1:12:26 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** FW: KEI e-mails: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas  
**Attachments:** KEI-Kathryn Ardizzone's e-mails.pdf; KEI-James Love's e-mails.pdf; KEI, UACT Comments, Proposed License to Retargeted Therapeutics (85 FR 31193).pdf

Good Morning Mark,

Attached please find all the e-mails that I have received so far from KEI. Also, attached is a formal comment letter from KEI that was received yesterday evening.

Best regards,

Vidita

**From:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Sent:** Monday, June 8, 2020 7:38 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi,

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Vidita also received additional ones, which she will be forwarding to you separately. We received KEI's formal comments this evening, but I won't be able to look at them until COB tomorrow at the earliest.

Thanks for your help.

Regards,  
**Bruce Goldstein, Esq., Director**  
NHLBI Office of Technology Transfer & Development

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Monday, June 8, 2020 4:11 PM  
**To:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**b5**



b5

**From:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Sent:** Monday, June 8, 2020 3:51 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Subject:** FW: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Hi Mark,

As you can see,

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While I do not feel

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What do you think about adding this:

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Regards,

**Bruce Goldstein, Esq., Director**

NHLBI Office of Technology Transfer & Development

**From:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>  
**Sent:** Monday, June 8, 2020 3:22 PM  
**To:** Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>  
**Subject:** FW: Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Monday, June 8, 2020 3:17 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <vidita.choudhry@nih.gov>; James Love <james.love@keionline.org>  
**Subject:** Follow-up Question

Hi Dr. Choudhry,

This is Kathryn Ardizzone from KEI, just following up on the phone call from a moment ago. I asked you if you could tell us who the principal officers of Retargeted Therapeutics are. As you know, Retargeted Therapeutics is the proposed licensee of the proposed license due today, described here: <https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>.

Sometime today, can you please tell us who the principal officers are? This is important and relevant to whether the license serves the public interest, and whether Retargeted has the ability to bring the license to practical application.

This information is not publicly available online so there is no way for us to obtain this information without your assistance.

Thank you in advance for your cooperation.

REL0000025165

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** Kathryn Ardizzone <[kathrynardizzonekei@gmail.com](mailto:kathrynardizzonekei@gmail.com)>  
**Sent:** Sunday, June 7, 2020 4:47 PM  
**To:** Choudhry, Vidita (NIH/NHLBI) [E] <[vidita.choudhry@nih.gov](mailto:vidita.choudhry@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

Dear Dr. Choudhry:

I was wondering if you might have a chance to answer the questions I sent you last week about the Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas before the deadline to submit comments tomorrow.

Also, I noticed that the prospective licensee, **Retargeted Therapeutics**, is not registered to do business in Delaware (contrary to the Federal Register Notice) and it does not even maintain a website. Have you noted this discrepancy? Are you concerned?

As you know, exclusive patent licenses may not be granted unless the NIH finds that the public will be served by the granting of the license, as indicated by **the applicant's ability to bring the invention to practical application or otherwise promote the invention's utilization by the public.** 35 U.S.C. 209(a)(2).

How can the public be assured that a non-registered, non-entity with no public presence and no history of commercializing inventions will use this invention in a way that is beneficial to the public?

Please answer at your earliest convenience. Thank you for your attention to this important matter.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** [kathryn ardizzone](#)  
**To:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]; James Love](#)  
**Subject:** Follow-up Question  
**Date:** Monday, June 8, 2020 3:17:54 PM

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Hi Dr. Choudhry,

This is Kathryn Ardizzone from KEI, just following up on the phone call from a moment ago. I asked you if you could tell us who the principal officers of Retargeted Therapeutics are. As you know, Retargeted Therapeutics is the proposed licensee of the proposed license due today, described here: <https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>.

Sometime today, can you please tell us who the principal officers are? This is important and relevant to whether the license serves the public interest, and whether Retargeted has the ability to bring the license to practical application.

This information is not publicly available online so there is no way for us to obtain this information without your assistance.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@kcionline.org](mailto:kathryn.ardizzone@kcionline.org)  
(202) 332-2670

**From:** [kathryn ardizzone](#)  
**To:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]](#)  
**Cc:** [marion.ress@cancerunion.org](#); [James Love](#); [Claire Cassidy](#)  
**Subject:** Joint Comments, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas, 85 FR 31193, to the firm, Retargeted Therapeutics  
**Date:** Monday, June 8, 2020 5:26:41 PM  
**Attachments:** [KEL UACT Comments, Proposed License to Retargeted Therapeutics \(85 FR 31193\).pdf](#)

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Dear Dr. Choudry:

Attached, please find the comments of Knowledge Ecology International and the Union for Affordable Cancer Treatment regarding the "Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas," 85 FR 31193, to the firm, Retargeted Therapeutics.

Thank you in advance for your consideration of these comments, as required per 35 USC 209(e).

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**From:** [kathryn ardizzone](#)  
**To:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]](#)  
**Cc:** [James Love](#)  
**Subject:** Question, Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas  
**Date:** Thursday, June 4, 2020 9:51:42 AM

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Dear Dr. Choudhry:

Please answer the following questions (which have never been previously asked and are relevant to the statutory criteria under 35 U.S.C. 209) regarding the Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment of CD20 Expressing Lymphomas

(<https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>).

1. Who are the principal officers of the licensee, Retargeted Therapeutics? **It does not have a website.**
2. How much did the NIH spend to develop the patented invention?
3. What grants are associated with the patented invention?
4. Has the patented invention been investigated in any clinical trials? If so, what are their numbers?
5. What analysis did the NIH conduct before concluding that an exclusive license is a necessary incentive?
6. How has/will the NIH ensured that the scope of the license is not broader than necessary?
7. What is the proposed duration of the license?

Thank you in advance for your cooperation.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Counsel  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@kcionline.org](mailto:kathryn.ardizzone@kcionline.org)  
(202) 332-2670

**From:** [James Love](#)  
**To:** [kathryn.ardizzone](#)  
**Cc:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]](#)  
**Subject:** Re: Follow-up Question  
**Date:** Monday, June 8, 2020 4:23:32 PM

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The patent number for this invention seems wrong.

E-758-2013-1-EP-04

Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use  
Thereof

15,701,442.4000

Jan 8, 2015

Sep 18, 2019.

3,092,252 in FR notice.

On Mon, Jun 8, 2020 at 3:49 PM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:

Just to emphasize, providing an exclusive license to a mystery company, on an important cancer treatment, and then expecting the public to accept the secrecy, even though we have the right to comment under the statute, is pretty offensive.

On Mon, Jun 8, 2020 at 3:17 PM kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)> wrote:

Hi Dr. Choudhry,

This is Kathryn Ardizzone from KEI, just following up on the phone call from a moment ago. I asked you if you could tell us who the principal officers of Retargeted Therapeutics are. As you know, Retargeted Therapeutics is the proposed licensee of the proposed license due today, described here: <https://www.federalregister.gov/documents/2020/05/22/2020-11036/prospective-grant-of-an-exclusive-patent-license-antibody-based-therapy-for-the-treatment-of-cd20>.

Sometime today, can you please tell us who the principal officers are? This is important and relevant to whether the license serves the public interest, and whether Retargeted has the ability to bring the license to practical application.

This information is not publicly available online so there is no way for us to obtain this information without your assistance.

Thank you in advance for your cooperation.

Sincerely,

Kathryn Ardizzone, Esq.  
Counsel

..... Knowledge Ecology International  
..... 1621 Connecticut Avenue NW, Suite 500  
..... Washington, DC 20009  
..... [kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
..... (202) 332-2670

--

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--

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<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

**From:** [James Love](#)  
**To:** [kathryn.ardizzone](#)  
**Cc:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]](#)  
**Subject:** Re: Follow-up Question  
**Date:** Monday, June 8, 2020 4:34:43 PM

---

I'm sorry. Probably my mistake. Was this an EPO patent?

On Mon, Jun 8, 2020 at 4:22 PM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:  
The patent number for this invention seems wrong.

E-758-2013-1-EP-04  
Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use  
Thereof  
15,701,442.4000  
Jan 8, 2015  
Sep 18, 2019.  
3,092,252 in FR notice.

On Mon, Jun 8, 2020 at 3:49 PM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:  
Just to emphasize, providing an exclusive license to a mystery company, on an important cancer treatment, and then expecting the public to accept the secrecy, even though we have the right to comment under the statute, is pretty offensive.

On Mon, Jun 8, 2020 at 3:17 PM kathryn.ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)> wrote:

Hi Dr. Choudhry,

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Sometime today, can you please tell us who the principal officers are? This is important and relevant to whether the license serves the public interest, and whether Retargeted has the ability to bring the license to practical application.

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Thank you in advance for your cooperation.

Sincerely,



Kathryn Ardizzone, Esq.  
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Washington, DC 20009  
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--

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<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

**From:** James Love  
**To:** [kathryn.ardizzone](mailto:kathryn.ardizzone@keionline.org)  
**Cc:** Choudhry, Vidita (NIH/NHLBI) [E]  
**Subject:** Re: Follow-up Question  
**Date:** Monday, June 8, 2020 4:50:14 PM

---

Dr. Choudhry, if you need more time to figure who runs the company, you can extend the period to comment.

On Mon, Jun 8, 2020 at 4:34 PM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:  
I'm sorry. Probably my mistake. Was this an EPO patent?

On Mon, Jun 8, 2020 at 4:22 PM James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:  
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Antibody Targeting Cell Surface Deposited Complement Protein C3d and Use Thereof

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Jan 8, 2015

Sep 18, 2019.

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Sometime today, can you please tell us who the principal officers are? This is important and relevant to whether the license serves the public interest, and whether Retargeted has the ability to bring the license to practical application.

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Sincerely,

Kathryn Ardizzone, Esq.  
Counsel  
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1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

--

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[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

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<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

**From:** [James Love](#)  
**To:** [kathryn.ardizzone](#)  
**Cc:** [Choudhry, Vidita \(NIH/NHLBI\) \[E\]](#)  
**Subject:** Re: Follow-up Question  
**Date:** Monday, June 8, 2020 3:50:28 PM

---

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On Mon, Jun 8, 2020 at 3:17 PM kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)> wrote:

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<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 5/18/2020 4:13:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** US/UK lead push against global patent pool for Covid-19

From The Guardian ([https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-for-covid-19-drugs?CMP=Share\\_iOSApp\\_Other](https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-for-covid-19-drugs?CMP=Share_iOSApp_Other)) Note that industry's views only appear in the last paragraph. Good to see Jaimie Love hasn't let the coronavirus slow him down. I wonder how much IP Costa Rica will contribute to their patent pool...

## US and UK 'lead push against global patent pool for Covid-19 drugs'

Efforts to dilute world health assembly resolution on open licensing decried as 'appalling'

Ministers and officials from every nation will meet via video link on Monday for the annual world health assembly, which is expected to be dominated by efforts to stop rich countries monopolising drugs and future vaccines against Covid-19.

As some countries buy up drugs thought to be useful against the coronavirus, causing global shortages, and the Trump administration does deals with vaccine companies to supply America first, there is dismay among public health experts and campaigners who believe it is vital to pull together to end the pandemic.

While the US and China face off, the EU has taken the lead. The leaders of Italy, France, Germany and Norway, together with the European commission and council, called earlier this month for any innovative tools, therapeutics or vaccines to be shared equally and fairly.

"If we can develop a vaccine that is produced by the world, for the whole world, this will be a unique global public good of the 21st century," they said in a statement.

The sole resolution before the assembly this year is an EU proposal for a voluntary patent pool. Drug and vaccine companies would then be under pressure to give up the monopoly that patents allow them on their inventions, which means they can charge high prices, so that all countries can make or buy affordable versions.

In the weeks of negotiations leading up to the meeting, which is scheduled to last for less than a day, there has been a dispute over the language of the resolution. Countries with major pharmaceutical companies argue they need patents to guarantee sufficiently high prices in wealthy nations to recoup their research and development costs.

Even more fraught have been attempts to reinforce countries' existing rights to break drug and vaccine company patent monopolies if they need to for the sake of public health. A hard-fought battle over Aids drugs 20 years ago led to the World Trade Organization's Doha declaration on trade-related intellectual property (Trips) in favour of access to medicines for all, but the US, which has some of the world's biggest drug companies, has strongly opposed wording that would encourage the use of Trips.

Campaigners say the resolution expected to be passed by the world health assembly's 198 member states is along the right lines, but too weakly worded.



“In general, it is a disappointment, appalling really. There was better text that was rejected,” said Jamie Love, the director of the NGO Knowledge Ecology International. “The US, UK, Swiss and some others pushed against the WHO taking the lead in pushing for open licensing of patents and know-how for drugs and vaccines.

“In a global crisis like this, that has such a massive impact on everyone, you would expect the WHO governing body to have the backbone to say no monopolies in this pandemic. It’s one thing for a country to use its economic clout to buy preferential access to drugs or vaccines. It’s another to prevent others from manufacturing and expanding global supply.”

Oxfam’s health policy manager, Anna Marriott, said: “This week’s letter calling for a people’s vaccine, which was signed by more than 140 world leaders and experts, sets the bar for the scale of ambition we need to meet the challenge before us.

“As we approach the final stages of this resolution, we need to see health ministers raise their game to match this ambition. Any government that tries to block or dilute this resolution is risking lives and standing on the wrong side of history.”

A UK government spokesman said: “The UK has long supported affordable and equitable access to essential medicines, including in low and middle-income countries. We continue to support public-private partnerships for product development, and approaches such as non-exclusive voluntary licensing which promote affordable access for all while also providing incentives to create life-changing vaccines.”

Costa Rica will launch a voluntary patent pool later this month. Its president, Carlos Alvarado Quesada, said at the WHO last week: “The pandemic attacks the same in each country regardless of whether you have the resources or not. It attacks people around the world in the same way,.

“Only together with multilateralism, with that sort of leadership, can we defeat coronavirus, not with nationalism and being selfish. It is the time for solidarity. It is the time to work together to show humanity the best that we are made of, the opportunity to show our brotherhood as a whole.”

Wellcome published a poll on Sunday of 2,000 people in the UK which found 96% supported the idea that national governments should work together to ensure that treatments and vaccines can be manufactured in as many countries as possible and distributed globally to everyone who needs them.

“We need vaccines and treatments that will work for the world, and any advances must be available to all countries equally, without exception,” said Alex Harris, the head of global policy at Wellcome. “No country should consider reserving possible future vaccines and treatments for their use only.”

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) trade body says companies already share their intellectual property with low-income countries. “We have not been included in these discussions and have limited understanding of what exactly is being proposed, and how it is different from the various institutions already facilitating sharing of data, know-how” and intellectual property, it said in a statement.

“Voluntary patent pools already exist and many companies are already exploring collaborations and voluntary licences.”

--  
Joseph P. Allen  
President

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**From:** Knezevic, Vlado (NIH/NIDDK) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CD7FD096830401C88A2C03EC1916B3C-KNEZEVICV2]  
**Sent:** 5/13/2020 6:41:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Knezevic, Vlado (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd7fd096830401c88a2c03ec1916b3c-knezevicv2]; Niebylski, Charles (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3248b0e1497e439b94ce47c2f52b0268-niebylskicd]  
**Subject:** FW: Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity  
**Attachments:** Response to KEI Comments re License for Exendin-4 Gene Transfer to Kriya Therapeutics Inc..pdf

Here we go Mark – for your record.  
Thank you again for your help,

*Vlado*

---

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation

Technology Advancement Office (TAO)  
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)  
National Institutes of Health  
Department of Health & Human Services  
Building 12A, Room 3011  
Bethesda, MD 20817-5632  
Office phone: 301-435-5560  
Mobile: b6  
Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

[www.niddk.nih.gov](http://www.niddk.nih.gov)



**From:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>  
**Sent:** Wednesday, May 13, 2020 2:40 PM  
**To:** [kathryn.ardizzone <kathryn.ardizzone@keionline.org>](mailto:kathryn.ardizzone@keionline.org)  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>  
**Subject:** RE: Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Dear Ms. Ardizzone,  
Attached to this message is our response to your comments regarding the "Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity" to Kriya Therapeutics, Inc.  
Sincerely,

REL0000025174

**Vladimir Knezevic, MD**

Senior Advisor for Commercial Evaluation

Technology Advancement Office (TAO)  
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)  
National Institutes of Health  
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Building 12A, Room 3011  
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Office phone: 301-435-5560  
Mobile: b6  
Email: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)

[www.niddk.nih.gov](http://www.niddk.nih.gov)



**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Tuesday, April 28, 2020 5:12 PM

**To:** Knezevic, Vlado (NIH/NIDDK) [E] <[vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Comments re: Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity

Dear Dr. Knezevic:

Attached, please find the comments of Knowledge Ecology International and James Love regarding the "Prospective Grant of an Exclusive Patent License: AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity" to Kriya Therapeutics, Inc."

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

REL0000025174



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NIDDK  
12A South Drive, Room 3011  
Bethesda, MD 20892  
Office (301) 435-5560

May 13, 2020

Kathryn Ardizzone  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
+1.202.332.2670  
kathryn.ardizzone@keionline.org

**Subject:** Comments Submitted in Response to Federal Register Notice 2020-07706 (85 FR 20508), entitled "AAV Mediated Exendin-4 Gene Transfer to Salivary Glands To Protect Subjects From Diabetes or Obesity"

Dear Ms. Ardizzone:

Thank you for providing us with your comments regarding the above-referenced notice ("Notice"). As you indicated, your comments were submitted on behalf of two organizations, and we kindly request that you share our response with both parties.

Prior to posting the Notice, the NIDDK determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. Kriya Therapeutics, Inc. (Kriya) is start-up company with a website that provides information demonstrating their interest in developing treatments for diabetes and obesity and some of their qualifications.

NIDDK considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 35 U.S.C. § 209(a), 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied. As we have noted in the past, many of the questions and issues posed in your comments and email communications have nothing to do with the regulatory requirements set forth in the regulations. We refer you to our letter of Nov 26, 2019, which addressed in detail these recurring issues.

The technologies described in the Notice will be applied in the development of therapy for two very much related and intertwined chronic diseases/conditions – diabetes and obesity. Considering physiological connection and prevalence of both in the same population (according to WHO, obesity is a major independent risk factor for developing diabetes, and more than 90% of diabetics are overweight or obese), it is not possible to limit treatment to the one and not to the other. In addition, considering the magnitude of investment required to develop such products (as stated in our initial response to your inquiry, no clinical work was conducted, no optimization of vector delivery, no IND application has been drafted or filed at the FDA), and the high level of investment risk (there are already dozens of approved products for diabetes and obesity - this is a very competitive space, with multiple different pharmacologic targets and treatment modalities), we have determined that a degree of exclusivity is an appropriate incentive to the commercial partner. Granting exclusivity in this case is necessary to allow Kriya to enter this market and support creation of robust competition in the therapeutic space occupied by many different technologies and increasing the likelihood that products embodying the inventions secure regulatory approval and become available to the public.

Sincerely,

Vlado Knezevic, M.D.  
Senior Advisor for Commercial Evaluation

Vladimir  
Knezevic -S

Digitally signed by Vladimir  
Knezevic -S  
Date: 2020.05.13 14:28:10  
-04'00'

REL0000025174.0001

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**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/24/2020 9:54:07 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

FYI below for the final email to KEI

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Monday, February 24, 2020 4:54 PM  
**To:** 'kathryn ardizzone' <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; manon.ress@cancerunion.org; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>  
**Subject:** RE: Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Ms. Ardizzone,

Thank you for the jointly provided comments dated February 10, 2020 on the Prospective Grant of an Exclusive License to Stanford University for our co-owned invention related to Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2. The purpose of this proposed exclusive license is to consolidate rights from the three co-owner institutions with Stanford to allow them to take the lead in licensing the technology for commercial development on behalf of the co-owners.

Contrary to your comments in Part 1 of the "Discussion", the NIH does evaluate and consider the statutes and regulations under 35 U.S.C. § 209 and 37 C.F.R. § 404 for each contemplated exclusive license, including the conditions under 35 U.S.C. § 209(a)(1)-(2) as referenced in your comments. The license that is the subject of the referenced Notice is no exception to this review process and was reviewed and evaluated in light of the referenced statutes and regulations. Your questions and comments in Part 2 of the Discussion regarding the government's financial contribution to the development of the invention are not relevant to the criteria for the grant of an exclusive license. As I stated in my earlier email, this license has not yet been granted and therefore, the specific terms of the license are not yet set. Your recommendations regarding specific terms to be added to the license have been reviewed and noted. The remainder of your comments are either irrelevant to the criteria for granting an exclusive license or have been previously addressed by the NIH.

Best Regards,  
Rose Freel

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** kathryn ardizzzone <[kathryn.ardizzzone@keionline.org](mailto:kathryn.ardizzzone@keionline.org)>

**Sent:** Monday, February 10, 2020 6:20 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>; manon.ress@cancerunion.org; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>

**Subject:** Joint Comments, Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Dr. Freel:

Attached, please find the joint comments of Knowledge Ecology International, Union for Affordable Cancer Treatment, and Manon Ress, with respect to the "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2."

Thank you in advance for reviewing these comments. We look forward to receiving the NCI's response.

Sincerely,

Kathryn Ardizzzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzzone@keionline.org](mailto:kathryn.ardizzzone@keionline.org)

(202) 332-2670

---

**From:** Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]  
**Sent:** 6/24/2020 4:17:43 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** KEI comments for A-462-2019 and A-273-2020  
**Attachments:** A-462-2019 and A-273-2020 Response to KEI.docx; Joint KEI, UACT Comments Re Anti-CD33 CAR Licenses.pdf; Re\_ Questions, 85 FR 28966.pdf

Re: KEI comments for A-462-2019 (Senti Bio) and A-237-2020 (Vor Bio)  
NIH Technology: E-097-2018  
FRN publication: *Federal Register* Vol. 85, No. 94, pages 28966-28967

Hi Mark,

Attached are comments from KEI for the above referenced proposed exclusive licenses, a proposed response, and the emails that I received from KEI. Happy to discuss after you've had a chance to review.

Jim



**b5**

---

**From:** Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]  
**Sent:** 4/29/2020 4:05:49 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**Subject:** RE: Draft Response to KEI Objection  
**Attachments:** Response to KEI\_4-29-20.pdf

Hi All,

Thank you for edits. I sent the attached letter to KEI this morning. It includes minor changes from Dale's version, but is substantially equivalent.

Andy

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, April 28, 2020 5:56 PM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Cc:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Subject:** FW: Draft Response to KEI Objection

Andy: I agree with Dale's proposed edits. The date of my letter (fill in the blank in the draft) was Nov 26, 2019

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Tuesday, April 28, 2020 11:36 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Draft Response to KEI Objection

Thanks got it finally, what do you think of these edits?

Dale D. Berkley, Ph.D., J.D.  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, April 28, 2020 11:04 AM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>  
**Subject:** RE: Draft Response to KEI Objection

Open it with adobe

**From:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
**Sent:** Tuesday, April 28, 2020 10:49 AM  
**To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Draft Response to KEI Objection



Andy—I can't open the second file, the KEI response. Could you please resend?

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>  
**Sent:** Tuesday, April 28, 2020 10:23 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Subject:** Draft Response to KEI Objection

Hi Mark and Dale,

KEI's objection to my recent FR notice is attached, along with my draft response to the same. Please let me know if you have any questions or concerns.

Thank you,

Andy

**Andrew R. Burke, Ph.D.**  
Senior Technology Transfer Manager  
National Cancer Institute  
9609 Medical Center Drive, Rm 1E550  
Rockville, MD 20850

Direct: (240) 276-5484  
Email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI  
9609 Medical Center Drive, Suite 530  
Rockville, MD 20852  
Office (240) 276-5530  
Facsimile (240) 276-5504

April 29, 2020

Kathryn Ardizzone  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
+1.202.332.2670  
kathryn.ardizzone@keionline.org

**Subject:** Comments Submitted in Response to Federal Register Notice 2020-06922 (85 FR 18577), entitled  
“Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy”

Dear Ms. Ardizzone:

Thank you for providing us with your comments regarding the above-referenced notice (“Notice”). As you indicated, your comments were submitted on behalf of two organizations and we kindly request that you share our response with both parties.

Prior to posting the Notice, the NCI determined that the prospective licensee, Lyell Immunopharma, was qualified, both technically and financially, to be granted an exclusive license to the Government’s intellectual property in the specified fields of use. As you noted in your comments, Lyell draws on the expertise of acclaimed researchers and professionals in the field and partners having a proven record for bringing therapies to patients. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied. As we have noted on countless occasions, many of the questions and issues posed in your comments and email communications have nothing to do with the requirements set forth in the regulations. We refer you to our letter of November 26, 2019, which addressed in detail these recurring issues.

The technologies described in the Notice will be applied in the development of certain companion diagnostics and cell therapies for the treatment of cancer. Considering, for example, the magnitude of investment required to develop such products and the high level of investment risk, we have determined that a degree of exclusivity is an appropriate incentive to the commercial partner. Moreover, any exclusive license executed pursuant to the Notice would be limited to the narrow fields of use specified in the same. The limitations contained in these fields of use will allow for additional companies utilizing distinct technical approaches to further license the Government’s rights. This strategy helps to create robust competition in the therapeutic space occupied by these technologies and increases the likelihood that products embodying the inventions secure regulatory approval and become available to the public.

Sincerely,

**b6**

Andrew Burke, Ph.D.  
Senior Technology Transfer Manager

REL0000025186.0001

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**From:** Petrik, Amy (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4EC05A179F04067B61F20605E911E7C-PETRIKA]  
**Sent:** 8/14/2020 5:48:58 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Question about 83 FR 16376

FYI

**From:** Petrik, Amy (NIH/NIAID) [E]  
**Sent:** Friday, August 14, 2020 1:48 PM  
**To:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** RE: Question about 83 FR 16376

This technology has the potential to be useful for many coronavirus vaccines. As such, we consider it a platform technology. A platform technology is normally licensed non-exclusively or on an exclusive basis with multiple narrow fields of use.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 10:58 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Can you tell me why NIAID decided to go non-exclusive on this invention?

On Fri, Aug 14, 2020 at 10:55 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

NIAID's license negotiations are considered proprietary and I can't discuss the identity of parties or subjects of discussion.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 10:47 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Thank you. With Moderna?

On Fri, Aug 14, 2020 at 10:42 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

Yes, these are nonexclusive license agreements and there are others in negotiation.

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Friday, August 14, 2020 10:40 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you.

So I guess it's a non-exclusive license? Will there be future licenses?

Kathryn

On Fri, Aug 14, 2020 at 10:37 AM Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov> wrote:

Hi Kathryn,

The following organizations have licensed the technology discussed in the subject Federal Register notice (HHS Ref. No. E-234-2016):

Medigen Vaccine Biologics Corp.

Noachis Terra, Inc.

OncoSec Medical Incorporated

BioNTech AG

N4 Pharm UK Limited

Dynavax Technologies

RNAceuticals, Inc.

Sanofi Pasteur

GlaxoSmithKline Biologicals SA

Adimmune Corporation

Vaxess Technologies

Meso Scale Diagnostics, LLC

The Binding Site Group Ltd.

Best,

Amy

**From:** Kathryn Ardizzone <[kathrynardizzonekei@gmail.com](mailto:kathrynardizzonekei@gmail.com)>

**Sent:** Thursday, August 13, 2020 4:19 PM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you for your response. Of course you understand that the FOIA requires agencies to produce records but does not PRECLUDE agency officials from answering members of the public's questions. I didn't ask for records, just a simple question. So a FOIA request would not be the proper route. In addition, I'm still awaiting a FOIA request from March that was granted expedited processing-- no word on a response almost 6 months later. But again, I don't have to go through the FOIA. You could just answer my question. It's a very simple matter that the public has the right to know the basic fact over whether a license to a publicly-owned technology was executed.

What is keeping you from answering my question? Your confidentiality agreement with Moderna?

Best,

Kathryn

On Thu, Aug 13, 2020 at 4:13 PM Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)> wrote:

Dear Kathryn,

Such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests:

[www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests](http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests)

Best,

Amy

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Tuesday, August 11, 2020 8:58 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Question about 83 FR 16376

Dear Ms. Petrik,

Has the NIH ever executed a license over the technology listed as available for licensing here: <https://www.federalregister.gov/documents/2018/04/16/2018-07822/government-owned-inventions-availability-for-licensing>? If so, who is the licensee? When was the license executed?

Thank you,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

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Washington, DC 20009

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--

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Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670



---

**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 2/7/2020 8:00:51 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Goldstein, Bruce (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]  
**Subject:** NIHtoKEI re OcQuila 7Jan2020.docx  
**Attachments:** NIHtoKEI re OcQuila 7Jan2020.docx

Dale, Mark, and Bruce – I realized I haven't yet responded to KEI's formal letter in response to our FR notice of intent to grant OcQuila an exclusive. b5

Please have a look at this response to KEI's letter so that I can send it out and clear this off my plate.

Thanks!

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,  
and Blood Institute

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
o. 301.435.5019  
[shmilovm@nih.gov](mailto:shmilovm@nih.gov)

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**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 2/7/2020 5:44:42 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Hi Mark,

See below for the email I just sent to KEI.

Best,  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Friday, February 7, 2020 12:44 PM  
**To:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Subject:** RE: Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Kathryn,

Regarding your separately emailed question about the press release from CHOP, that press release is related to a different technology that is the subject of a separate patent family.

This invention is at the preclinical stage of development and therefore, no clinical trials have commenced. The invention was jointly developed between researchers at the NCI, Stanford and CHOP and is co-owned by the three institutions. The contemplated license is for the purpose of consolidating rights of the three co-owners to allow Stanford to take the lead on behalf of all the co-owners. The intention of the prospective license is to expedite the commercial development of the invention.

The remainder of your questions have either been asked on previous prospective licenses and the answers for this license are the same or they are not relevant to the criteria for granting an exclusive license. The terms for this license are not yet determined as this license is not yet completed. Our license templates are readily available to the public, however, the specific terms related to this license are business confidential.

Best Regards,  
Rose

--

Rose Santangelo Freel, Ph.D.  
Senior Technology Transfer Manager  
**National Cancer Institute**

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>

**Sent:** Thursday, February 6, 2020 4:07 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Subject:** Questions regarding Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

Dear Ms. Freel:

At your earliest convenience, please answer the following questions regarding "Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2":

1. What is the development stage of the invention? Have any clinical trials investigating it commenced? If so, what are their numbers?
2. What was the NCI's role in developing the invention, and how does it relate to that of Stanford and CHOP?
3. Please provide an estimate of what the NCI has spent in developing the invention, and list any grant numbers associated with it.
4. What is the proposed duration of the license?
5. On what basis did the NIH conclude that an exclusive patent license is a necessary incentive?
6. How will the NIH limit the scope of the license to not broader than the necessary incentive?
7. How will the NIH share in any royalties paid by a sublicensee to Stanford? 8. How will the license ensure that NIH receives a reasonable return on its investment in the invention?
9. Has the NIH sought the antitrust advice of the U.S. Attorney General concerning the license?

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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**From:** Petrik, Amy (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4EC05A179F04067B61F20605E911E7C-PETRIKA]  
**Sent:** 8/14/2020 2:37:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Question about 83 FR 16376

As requested – thanks, Mark.

**From:** Petrik, Amy (NIH/NIAID) [E]  
**Sent:** Friday, August 14, 2020 10:37 AM  
**To:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** RE: Question about 83 FR 16376

Hi Kathryn,

The following organizations have licensed the technology discussed in the subject Federal Register notice (HHS Ref. No. E-234-2016):

Medigen Vaccine Biologics Corp.  
Noachis Terra, Inc.  
OncoSec Medical Incorporated  
BioNTech AG  
N4 Pharm UK Limited  
Dynavax Technologies  
RNAceuticals, Inc.  
Sanofi Pasteur  
GlaxoSmithKline Biologicals SA  
Adimmune Corporation  
Vaxess Technologies  
Meso Scale Diagnostics, LLC  
The Binding Site Group Ltd.

Best,  
Amy

**From:** Kathryn Ardizzone <kathrynardizzonekei@gmail.com>  
**Sent:** Thursday, August 13, 2020 4:19 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** Re: Question about 83 FR 16376

Hi Amy,

Thank you for your response. Of course you understand that the FOIA requires agencies to produce records but does not PRECLUDE agency officials from answering members of the public's questions. I didn't ask for records, just a simple question. So a FOIA request would not be the proper route. In addition, I'm still awaiting a FOIA request from March that was granted expedited processing-- no word on a response almost 6 months later. But again, I don't have to go through the FOIA. You could just answer my question. It's a very simple matter that the public has the right to know the basic fact over whether a license to a publicly-owned technology was executed.

What is keeping you from answering my question? Your confidentiality agreement with Moderna?

Best,  
Kathryn

On Thu, Aug 13, 2020 at 4:13 PM Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)> wrote:

Dear Kathryn,

Such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests:

[www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests](http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests)

Best,

Amy

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Tuesday, August 11, 2020 8:58 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Question about 83 FR 16376

Dear Ms. Petrik,

Has the NIH ever executed a license over the technology listed as available for licensing here: <https://www.federalregister.gov/documents/2018/04/16/2018-07822/government-owned-inventions-availability-for-licensing>? If so, who is the licensee? When was the license executed?

Thank you,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

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Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)

(202) 332-2670

**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]  
**Sent:** 8/4/2020 8:13:48 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Vathyam, Surekha (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ed61806c5bf4e9a819ddb37e91dee70-vathyams]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Thanks!

I'll put together a draft b5 and kick it back to you for review.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, August 4, 2020 4:06 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Alternatively, b5

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, August 4, 2020 4:02 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

I don't recall b5 I would suggest:

**b5**

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Tuesday, August 4, 2020 3:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>

**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark,

I've confirmed [b5] I'll work with you to develop a draft response.

We agreed to [b5]  
[b5]

Thanks,

Mike

**From:** Harper, Jill (NIH/NIAID) [E] <jharper@niaid.nih.gov>

**Sent:** Thursday, July 30, 2020 8:39 PM

**To:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>

**Cc:** Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Sullivan, Fantasia (NIH/NIAID) [C] <fantasia.sullivan@nih.gov>; Fowler, Karen (NIH/NIAID) [C] <fowlerk@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] <auchinclossh@niaid.nih.gov>

**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mike and Surekha, please see below and attached, and let's discuss early next week.

Thanks,  
Jill

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**From:** "Fauci, Anthony (NIH/NIAID) [E]" <afauci@niaid.nih.gov>

**Date:** Thursday, July 30, 2020 at 7:51:28 PM

**To:** "Harper, Jill (NIH/NIAID) [E]" <jharper@niaid.nih.gov>

**Cc:** "Conrad, Patricia (NIH/NIAID) [E]" <conradpa@niaid.nih.gov>, "Barasch, Kimberly (NIH/NIAID) [C]" <kimberly.barasch@nih.gov>

**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Jill:

Please look into this and take care of it.

[b5]

Thanks,  
Tony

**From:** James Love <james.love@keionline.org>

**Sent:** Thursday, July 30, 2020 11:59 AM

**To:** Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>

**Cc:** Paul Davis <pdavisx@gmail.com>; Sawyer, Eric <ERICLSAWYER@gmail.com>; Brook Baker <b.baker@northeastern.edu>; Thiru Balasubramaniam <thiru@keionline.org>; Morten, Christopher <christopher.morten@nyu.edu>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Peter Maybarduk <pmaybarduk@citizen.org>; lumbasia@citizen.org; Luis Villalon <info@innovarte.cl>; Merith Basey

REL0000025203



<merith@essentialmedicine.org>; lpma75@gmail.com; Gopa Kumar <kumargopakm@gmail.com>; Sangeeta <sangeeta@twnetwork.org>; Umunyana Rugege <rugege@section27.org.za>; Ngqabutho Mpofu <ngqabutho.mpofu@mail.tac.org.za>; Manuel MARTIN <Manuel.MARTIN@geneva.msf.org>; Yuanqiong HU <Yuanqiong.HU@geneva.msf.org>

**Subject:** Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Dr. Fauci,

Attached is a letter from several individuals and groups, asking that NIAID not grant exclusive rights in a HIV patent license for South Africa, India and other low income countries.

The license is to RNAceuticals, a firm without a web page. The technology is for N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains.

This letter addresses a narrow issue, the geographic scope of the license, and it asks that exclusivity does not extend to countries like South Africa and India, that have per capita incomes less than 30 percent of the United States.

Among the groups signing are the leading patient group for persons living with HIV in South Africa, where an estimated 19 percent of persons from 19 to 49 are living with HIV, and patient advocacy groups working in Southeast Asia, India, Brazil, Chile, Mexico, Ecuador, Argentina, Colombia, and Guatemala, as well as several US and globally based health groups and patient advocates.

Jamie

--

James Love. Knowledge Ecology International  
U.S. Mobile +1.202.361.3040  
U.S. office phone +1.202.332.2670  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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**From:** Petrik, Amy (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4EC05A179F04067B61F20605E911E7C-PETRIKA]  
**Sent:** 8/14/2020 5:53:54 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Question about 83 FR 16376

OK, thanks! Sorry, I sent it just before I received your message with the last suggestion.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, August 14, 2020 1:53 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Subject:** RE: Question about 83 FR 16376

b5

**From:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Sent:** Friday, August 14, 2020 1:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Question about 83 FR 16376

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, August 14, 2020 1:52 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Subject:** RE: Question about 83 FR 16376

b5

**From:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Sent:** Friday, August 14, 2020 1:49 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Question about 83 FR 16376

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Friday, August 14, 2020 1:49 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Subject:** RE: Question about 83 FR 16376

b5

Thanks

**From:** Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>  
**Sent:** Friday, August 14, 2020 1:47 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: Question about 83 FR 16376

Good idea – I'll make that change.

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 1:47 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

One small thing.

b5

b5

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Sent:** Friday, August 14, 2020 1:44 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Thanks for your input and time on this!

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 1:43 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Looks great to me

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Sent:** Friday, August 14, 2020 1:41 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Yes,

b5

b5

So I'll send this, unless there are edits/objections:

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 1:31 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

I think

b5

b5

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Sent:** Friday, August 14, 2020 1:04 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

OK, b5 would the following be acceptable?

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Sent:** Friday, August 14, 2020 12:54 PM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

I would suggest b5

b5

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Friday, August 14, 2020 12:18 PM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

Right, so b5 I would think that b5

b5

b5

Best, Dale

**Dale D. Berkley, Ph.D., J.D.**

NIH Branch

Office of The General Counsel

9000 Rockville Pike

Building 31, 2B-47

Office: 301-496-6043

Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Sent:** Friday, August 14, 2020 11:58 AM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

REL0000025205

**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

b5

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Friday, August 14, 2020 11:54 AM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

We can give them the answer. But first, tell me the answer if you would.

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Sent:** Friday, August 14, 2020 11:42 AM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

Another last question – they’ve asked “Can you tell me why NIAID decided to go non-exclusive on this invention?”

b5

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>

**Sent:** Friday, August 14, 2020 10:51 AM

**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

Right,

b5

b5

**Dale D. Berkley, Ph.D., J.D.**

NIH Branch

Office of The General Counsel

9000 Rockville Pike

Building 31, 2B-47

Office: 301-496-6043

Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>

**Sent:** Friday, August 14, 2020 10:49 AM

**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>

**Cc:** Felliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>

**Subject:** RE: Question about 83 FR 16376

One last question – can

b5

want to be sure.

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 10:32 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

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**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Sent:** Friday, August 14, 2020 10:29 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>; Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Would it be

b5

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**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 10:09 AM  
**To:** Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Cc:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

b5

Dale

**From:** Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>  
**Sent:** Friday, August 14, 2020 10:05 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>; Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Hi Dale,

I was wondering about

b4,b5

b4,b5

Carol

**From:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Sent:** Friday, August 14, 2020 9:16 AM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Cc:** Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>; Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: Question about 83 FR 16376

Amy:

# b5

Let me know if you want to discuss. I'm copying Mark for awareness.

Best, Dale

**Dale D. Berkley, Ph.D., J.D.**  
NIH Branch  
Office of The General Counsel  
9000 Rockville Pike  
Building 31, 2B-47  
Office: 301-496-6043  
Email: [Berkleyd@nih.gov](mailto:Berkleyd@nih.gov)

**From:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Sent:** Friday, August 14, 2020 8:13 AM  
**To:** Berkley, Dale (NIH/OD) [E] <[berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)>  
**Cc:** Salata, Carol (NIH/NIAID) [E] <[csalata@niaid.nih.gov](mailto:csalata@niaid.nih.gov)>; Feliccia, Vincent (NIH/NIAID) [E] <[vfeliccia@niaid.nih.gov](mailto:vfeliccia@niaid.nih.gov)>  
**Subject:** FW: Question about 83 FR 16376

Hi Dale,

Please see the email string below. How would you advise that we proceed?  
Happy to speak by phone. I'm free except for 1:30pm-2pm and 3-3:30pm today.

Thanks,  
Amy

**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Sent:** Thursday, August 13, 2020 7:53 PM  
**To:** Kathryn Ardizzone <[kathrynardizzonekei@gmail.com](mailto:kathrynardizzonekei@gmail.com)>  
**Cc:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Subject:** Re: Question about 83 FR 16376

Amy, is the Director's office telling you to stonewall KEI?

Jamei

On Thu, Aug 13, 2020 at 4:20 PM Kathryn Ardizzone <[kathrynardizzonekei@gmail.com](mailto:kathrynardizzonekei@gmail.com)> wrote:

Hi Amy,

Thank you for your response. Of course you understand that the FOIA requires agencies to produce records but does not PRECLUDE agency officials from answering members of the public's questions. I didn't ask for records, just a simple question. So a FOIA request would not be the proper route. In addition, I'm still awaiting a FOIA request from March that was granted expedited processing— no word on a response almost 6 months later. But again, I don't have to go through the FOIA. You could just answer my question. It's a very simple

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matter that the public has the right to know the basic fact over whether a license to a publicly-owned technology was executed.

What is keeping you from answering my question? Your confidentiality agreement with Moderna?

Best,  
Kathryn

On Thu, Aug 13, 2020 at 4:13 PM Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)> wrote:

Dear Kathryn,

Such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests:

[www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests](http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests)

Best,

Amy

**From:** kathryn ardizzone <[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)>  
**Sent:** Tuesday, August 11, 2020 8:58 PM  
**To:** Petrik, Amy (NIH/NIAID) [E] <[amy.petrik@nih.gov](mailto:amy.petrik@nih.gov)>  
**Cc:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Question about 83 FR 16376

Dear Ms. Petrik,

Has the NIH ever executed a license over the technology listed as available for licensing here: <https://www.federalregister.gov/documents/2018/04/16/2018-07822/government-owned-inventions-availability-for-licensing>? If so, who is the licensee? When was the license executed?

Thank you,

Kathryn Ardizzone, Esq.

Counsel

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Knowledge Ecology International

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[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 11/7/2019 4:58:08 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** Kite and Intima appeals from KEI  
**Attachments:** Letter to KEI and Ms. Love 11-5-2019.docx; Administrative Appeal NIH Licenses to Kite in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20.pdf; Joint Administrative Appeal, NIH Exclusive License to Intima Bioscience (2).pdf

Mark:

The attached draft letter to KEI

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I've attached the source documents (sans attachments) for your convenience.

Let me know what you think.

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
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**b5**

**b5**



**b5**



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September 13, 2019

Karen Rogers  
Acting Director  
Office of Technology Transfer  
6011 Executive Blvd  
Suite 325  
Rockville, MD 20852  
Via email: [rogersk@mail.nih.gov](mailto:rogersk@mail.nih.gov)

**Re: Appeal, Exclusive Licenses in Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20 to Kite Pharma, Inc., a Wholly-Owned Subsidiary of Gilead Sciences, as Described in Federal Register Notices 84 FR 33270 and 84 FR 33272**

Dear Ms. Rogers:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Universities Allied for Essential Medicines (UAEM), Social Security Works (SSW), and Clare Love (collectively, "Appellants"), write to appeal the decision of the National Institutes of Health (NIH) to grant exclusive licenses in "Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20" to Kite Pharma, Inc. ("Kite"), a wholly-owned subsidiary of Gilead Sciences ("Gilead"), as described in 84 FR 33270 and 84 FR 33272.

This appeal addresses six important issues:

1. Did the NIH properly evaluate the necessity of granting an exclusive license, for example, by considering other incentives such as FDA regulatory protection of test data, and patent protection from non-NIH patent holders?
2. Assuming that the NIH can establish that an exclusive license was necessary in this case, did the NIH meet its statutory responsibility to limit the scope of rights to that which is "reasonably necessary" to induce the investment required to bring the invention to practical application, for example by analyzing the expected costs of investment and annual revenues to determine how many years of exclusivity are warranted?

3. Did the NIH request the antitrust advice of the Attorney General, pursuant to 40 U.S.C. § 559?
4. Will the licenses tend to substantially lessen competition by creating undue market concentration, in violation of 35 U.S.C. § 209(a)(4)?
5. Was the public's right to evaluate a proposed license under 35 U.S.C. § 209(e) undermined by the NIH's lack of transparency?
6. Has the NIH done anything to implement the objectives in the Public Health Service (PHS) Technology Transfer Policy Manual regarding promoting access in developing countries?

We request a hearing on this appeal.

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## A. BACKGROUND AND PROCEDURAL HISTORY

The licenses at issue grant Gilead exclusive rights to manufacture and sell a chimeric antigen receptor (CAR or CAR T) therapy designed to treat B-cell lymphomas and leukemia.

Two CAR therapies have received FDA approval to treat hematological cancers: Kymriah® (tisagenlecleucel-T), sold by Novartis for \$475,000 per treatment,<sup>1</sup> and Yescarta® (axicabtagene ciloleucel), sold by Gilead for \$373,000 per treatment.<sup>2</sup> Hospital bills could bring total costs to receive the treatments as high as \$1.5 million.<sup>3</sup>

CAR treatments have not been widely accessible to patients, in part due to questions about whether hospitals will be reimbursed for the costs of the treatment, which is exclusive of the hospital stays necessary to administer CAR therapies and care for their potential side effects.

The CAR inventions at issue here, as well as KEI’s correspondence about the licenses with the NIH and the procedural history of this appeal, are discussed below.

<sup>1</sup> Matthew Harper, *Patient Advocate Says Novartis’ \$475,000 Breakthrough Should Cost Just \$160,000*, *Forbes.com*, February 8, 2018, available at <https://www.forbes.com/sites/matthewharper/2018/02/08/patient-advocate-says-novartis-475000-breakthrough-should-cost-just-160000/#13e8be1b5152>.

<sup>2</sup> Toni Clarke, Bill Berkrot, *FDA Approves Gilead cancer gene therapy; price set at \$373,000*, *Reuters*, October 18, 2017, available at <https://www.reuters.com/article/us-gilead-sciences-fda/fda-approves-gilead-cancer-gene-therapy-price-set-at-373000-idUSKBN1CN35H>.

<sup>3</sup> Liz Szabo, *Cascade of Costs Could Push New Gene Therapy Above \$1 Million Per Patient*, *Kaiser Health News*, Kaiser Health News, October 17, 2017, available at <https://khn.org/news/cascade-of-costs-could-push-new-gene-therapy-above-1-million-per-patient/>.



### The Inventions

On July 12, 2019, the NIH published two notices of proposed exclusive licenses in the Federal Register: (1) Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 (84 FR 33270);<sup>4</sup> and (2) Prospective Grant of an Exclusive Patent License: Autologous Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 (84 FR 33272).<sup>5</sup>

The licenses involve the same intellectual property (Bicistronic Chimeric Antigen Receptor (CAR) Constructs Targeting CD19 and CD20, U.S. Provisional Patent Application No. 62/732,263), the same prospective licensee (Kite Pharma), and the same terms (exclusive, worldwide rights). They differ in their application. The first license would pertain to an *allogeneic* use of CAR targeting CD19 and CD20, while the second license pertains to *autologous* use.

The potential indications of the subject technology are “B cell malignancies expressing CD19, CD20, or both.”<sup>6</sup> According to the Federal Register notices, “CD19 and CD20 are expressed on the cell surface of several hematological malignancies, including Non-Hodgkins Lymphoma (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL).”<sup>7</sup>

### Correspondence about the Licenses between KEI and the NIH

On July 12, 2019, Claire Cassedy, Research Associate and Assistant for Development with KEI, emailed Dr. David Lambertson, Senior Technology Transfer Officer with the National Cancer Institute (NCI), a list of ten questions designed to elicit information about whether the prospective licenses satisfy federal law and regulations governing the licensing of federally-owned technology.<sup>8</sup>

Dr. Lambertson responded on July 16, 2019. Of the 10 questions submitted by Ms. Cassedy, he answered only Questions 6, 8, and 9, erroneously stating that “[t]he other questions either ha[d] been answered previously or [were] not related to the criteria set forth in federal regulations.”<sup>9</sup>

KEI Director James Love responded to Dr. Lambertson by email dated July 16, 2019, explaining the relevance of Ms. Cassedy’s questions to the criteria governing exclusive licenses.<sup>10</sup> Dr. Lambertson did not respond to that email.

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<sup>4</sup> 84 Fed. Reg. 33270 (July 12, 2019).

<sup>5</sup> 84 Fed. Reg. 33272 (July 12, 2019).

<sup>6</sup> <https://www.ott.nih.gov/technology/e-205-2018>.

<sup>7</sup> 84 FR 33270; 84 FR 33272.

<sup>8</sup> See Attachment A.

<sup>9</sup> See *id.*

<sup>10</sup> See Attachment B.

Later that day, Mr. Love sent Dr. Lambertson an email asking why he refused to state whether the subject inventions were developed pursuant to a Cooperative Research and Development Agreement (CRADA) between the NIH and Kite. Dr. Lambertson did not respond to that email.<sup>11</sup>

Also on July 16, 2019, Mr. Love emailed Dr. Lambertson asking about the cost of manufacturing CAR T cells.<sup>12</sup> Dr. Lambertson responded, by email dated July 17, 2019, that he did not have access to such information.<sup>13</sup> Mr. Love replied by email that same day, asking who, within the NIH, does have access to such information.<sup>14</sup> Dr. Lambertson did not respond.

#### July 29, 2019 Comments

KEI timely submitted comments on the prospective licenses to the NIH on July 29, 2019, joined by UACT, SSW, UAEM, and Clare Love, a cancer patient who has suffered from lymphoma, one of the potential indications of the licensed invention.<sup>15</sup>

#### Final Determination Letters

On August 14, 2019, Dr. Lambertson emailed KEI two PDF documents which represented the final determinations of the National Cancer Institute regarding the licenses and which articulated the NCI's rationale for proceeding with the licenses over KEI's objections. The two documents, which are identical except that each pertains to a separate license, state that the comments did not persuade the NCI that the licenses were inconsistent with federal law.

The final determination letters are attached herein.<sup>16</sup>

### **B. STANDING**

A right to appeal an exclusive license is afforded to: (1) A person whose license has been denied; (2) A licensee whose license has been modified or terminated, in whole or in part; or (3) A person who timely filed a written objection in response to the notice . . . and who can demonstrate . . . that such person may be damaged by the agency action. 37 C.F.R § 404.11(a).

Appellants satisfy the third basis for an appeal. We timely submitted our comments to the NIH, and appellant Clare Love is a lymphoma patient who could be damaged by the licenses.

---

<sup>11</sup> See Attachment C.

<sup>12</sup> See Attachment D.

<sup>13</sup> See *id.*

<sup>14</sup> See Attachment E.

<sup>15</sup> See Attachment F.

<sup>16</sup> See Attachments G, H.

An overly broad exclusive license that is inconsistent with 35 U.S.C. § 209 not only violates federal law but could harm patients, such as Mr. Love, who may need to access the licensed technology but could face unnecessary barriers to accessing the treatments, due to cost.

Also, KEI has had to divert resources in order to counteract the NIH's unlawful lack of transparency, which has frustrated KEI's mission.

### C. ARGUMENT

Appellants appeal the NIH's decision to proceed with the licenses for the following six reasons:

1. The NIH did not properly evaluate the necessity of granting an exclusive license, for example, by considering other incentives such as FDA regulatory protection of test data, and patent protection from non-NIH patent holders;
2. Assuming that the NIH could establish that an exclusive license was necessary in this case, the NIH did not meet its statutory responsibility to limit the scope of rights to that which is "reasonably necessary" to induce the investment required to bring the invention to practical application, for example by analyzing the expected costs of investment and annual revenues to determine how many years of exclusivity are warranted;
3. The NIH did not request the advice of the Attorney General regarding whether the licenses would create or maintain a violation of federal antitrust laws;
4. The licenses violate 35 U.S.C. § 209(a)(4) because they will tend to substantially lessen competition by creating undue market concentration;
5. The public's right to evaluate a proposed license under 35 U.S.C. § 209(e) was undermined by the NIH's lack of transparency; and
6. The NIH has not done anything to implement to objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

This appeal addresses each issue in turn.

1. The licenses violate 35 U.S.C. § 209(a)(1) because the NIH did not properly evaluate the necessity of granting an exclusive license, for example, by considering other incentives such as FDA regulatory protection of test data, and patent protection from non-NIH patent holders.

Section 209 of the Bayh-Dole Act allows a federal agency to grant an exclusive license only if "granting the license is a reasonable and necessary incentive to . . . (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public[.]" 35 U.S.C. § 209(a)(1).

It is our understanding that the NIH has not undertaken a serious evaluation of the adequacy of existing incentives and subsidies, relating to practical application of the inventions, in order to evaluate whether or not granting an exclusive license was a "reasonable and necessary incentive."



Our comments note that in the United States, Gilead/Kite and Novartis have both received seven years of Orphan Drug exclusivity for Yescarta and Kymriah, as well as 12 year of test data protection.<sup>17</sup> In the European Union, those protections are 10 and 11 years, respectively. Similar protections exist in Japan, Canada, and in many other countries.

**Table 1: Three U.S. Orphan Designations and Approvals for Yescarta and Two Orphan Designations and Approvals for Kymriah**

<u>Product</u>	<u>Basis of Designation</u>	<u>Date of Designation</u>
axicabtagene ciloleucel	Treatment of follicular lymphoma	04/25/201
axicabtagene ciloleucel	Treatment of primary mediastinal B-cell lymphoma	04/20/2016
axicabtagene ciloleucel	Treatment of diffuse large B-cell lymphoma	03/27/2014
tisagenlecleucel	For the treatment of acute lymphoblastic leukemia	01/31/2014
tisagenlecleucel	Treatment of diffuse large B-cell lymphoma	02/03/2015

We also note that the FDA granted Novartis a priority review voucher for Kymriah,<sup>18</sup> an incentive that we estimate to be worth at least \$80 million in the current market.

The NIH must take into consideration the likelihood that the new technologies will receive Orphan Drug market exclusivities and/or priority review vouchers, and evaluate the incentive that the 12 years of test data provides, even in the absence of an exclusive patent license.

The NIH/NCI's final determination letters do not address our argument about the necessity of granting additional exclusivities to Gilead as an incentive to market the technology. Rather, after briefly addressing competition-related issues, the letters conclusorily state: "Your other questions and statements either have been addressed in many previous responses to you or are not relevant to the statutory criteria for licensing."<sup>19</sup>

<sup>17</sup> <https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=463114>; <https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=423914>.

<sup>18</sup> 82 Fed. Reg. 42686 (Sept. 11, 2017).

<sup>19</sup> See Attachments G & H.



NIH has never addressed our arguments regarding the necessity of granting these specific exclusive licenses. As such, the NIH apparently takes the view that it is not required to consider that issue, in direct contradiction with 35 U.S.C. § 209(a)(1).

2. Assuming that the NIH could establish that an exclusive license was necessary in this case, the licenses violate 35 U.S.C. § 209(a)(2) because the NIH did not meet its statutory responsibility to limit the scope of rights to that which is “reasonably necessary” to induce the investment required to bring the invention to practical application, including in particular the number of years of exclusivity.

When proposing to license government-owned technology on an exclusive basis, a federal agency must not only determine whether exclusivity is a reasonable and necessary incentive to encourage a licensee to commercialize the licensed invention. Rather, before granting the license, the agency must also determine “that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” 35 U.S.C. § 209(a)(2).

The scope of a license in federally-sponsored technology may vary along the following (non-exhaustive) parameters:

- The period of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (*i.e.*, five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (*i.e.*, targeted diseases).

The scope of the license must not exceed the incentive needed to induce a company to bring a government-owned invention to market. Factors that pertain to the necessary incentive include:

- The expected profitability of the invention;
- The costs of financing research and development and bringing the invention to market, including obtaining FDA approval;
- The government’s investment in R&D and the development stage of the technology; and
- The cost to manufacture the invention.

*a. It appears that the NIH has not performed the necessary analysis to determine the appropriate scope of the licenses.*

For several reasons, it appears that the NIH has not performed the necessary analysis to determine the appropriate scope of the licenses.

First, as indicated by its response to KEI’s questions regarding the licenses, the NIH appears to hold the erroneous view that information such as the government’s contribution to the licensed technology and the stage of research and development of the invention is irrelevant to Section

209. That view is confirmed by the brief analysis in NIH's final determinations about the licenses. After giving a perfunctory nod to our objections about the anticompetitive effects of the licenses, the NIH states that our "other questions and statements have either been addressed in many previous responses to you or are not relevant to the statutory criteria for licensing."<sup>20</sup>

One of the questions posed by KEI, that the NIH refused to answer in advance of the comment deadline and did not address in its final determination letters, was as follows:

"[H]as/will the NIH seek license terms that will ensure the resultant therapy is available to patients on reasonable terms?"<sup>21</sup>

It goes without saying that if the NIH views the issues presented by KEI as irrelevant, it does not consider them when executing licenses, in violation of the Bayh-Dole Act. But those issues relate directly to the criteria the NIH must consider under 35 U.S.C. § 209 and 37 C.F.R. § 404.7, since the incentive that is reasonably necessary is related to the prices that will be charged.

Rather than answering several of KEI's questions about the licenses, the NIH referred KEI to the NIH's past answers to questions about separate, unrelated licensing decisions. This strongly implies that the NIH assumes across-the-board positions about the appropriate scope of licenses without engaging in the individualized assessments mandated by Section 209.

One area in which the NIH fails to determine the appropriate scope of a license on a case-by-case basis is the duration of exclusivity.

The NIH's continued refusal to answer KEI's question about the duration of proposed licenses indicates that the NIH routinely grants licenses for the life of a patent, even though the number of years of exclusivity is directly and unambiguously related to the incentive to invest.

Recent correspondence between KEI and the NIH appears to confirm this. On August 20, 2019, KEI asked NIH Technology Transfer Officer Michael Shmilovich whether he was aware of any NIH exclusive licenses for which the term of the license is shorter than the term of the patent. Mr. Shmilovich responded that he did not "personally have any licenses on my docket granted for a term shorter than the full patent term" and that he was "unaware of any that may have been granted by my colleagues at other Institutes."<sup>22</sup>

This also seems to be confirmed by the NIH's model license agreements, which it publishes on its website,<sup>23</sup> and which serve as the basis of license negotiations.<sup>24</sup> The NIH's model Exclusive

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<sup>20</sup> See Attachments G & H.

<sup>21</sup> See Attachment A.

<sup>22</sup> See Attachment I.

<sup>23</sup> <https://www.ott.nih.gov/resources#MLA>.

<sup>24</sup> <https://www.ott.nih.gov/licensing>.

Patent License Agreement contains the following duration-of-exclusivity term: "This Agreement . . . shall extend to the expiration of the last to expire of the Licensed Patent Rights[.]"<sup>25</sup>

Finally, all of the NIH exclusive licenses granted by the NIH to Kite that were disclosed in Kite's annual and quarterly SEC reports extend until the expiration of the last-filed patent.<sup>26</sup> KEI has no objections to the NIH collecting royalties for the life of patents, and indeed, often this is precisely what the government should do. But the term of exclusive rights should be limited in years to be shorter than the term of the patents, as it has in the past for several NIH licenses.

The idea that the NIH may default to negotiating license agreements that last the entire life of a patent is concerning for several reasons. As a legal matter, if the term of exclusivity is life of patent, no matter what the facts are, then the NIH is no longer meeting the requirements of 35 U.S.C. § 209 to ensure that the "scope of exclusivity is not greater than reasonably necessary."

Factually, past experience refutes the notion that, in all cases, exclusivity extending for the life of a patent is necessary to incentivize a company to market the licensed technology. The NIH has granted licenses that were shorter than the life of a patent, and those collaborations succeeded.

In earlier years, the Department of Health and Human Services (HHS) regulated the term of exclusivity even for extramural funded inventions. For example, the cancer drug cisplatin (cisplatinum) was licensed to Bristol-Myers Squibb (BMS) by Research Corporation for a term of three years from the date of the first commercial sale in the United States, or eight years from the date of the exclusive license, whichever occurred first.<sup>27</sup> BMS petitioned HHS for and was granted an extension of the original exclusivity period to five years from the first commercial sale.<sup>28</sup> Before that exclusivity period expired, BMS requested a seven-year extension.<sup>29</sup> Several other companies competed for the license.<sup>30</sup> The NIH negotiated a five-year extension of the term with BMS, in order to incentivize additional research related to cisplatin, but in return BMS was required to lower the price of cisplatin by 30 percent<sup>31</sup> and contribute \$35 million to cancer

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<https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Patent-License-Exclusive-model-102015.pdf>. The Exclusive Patent Agreement provides grounds for earlier termination, such as if the licensee commits a material breach of the agreement or fails to commercialize the technology, but what KEI here seeks to emphasize is the fact that the default license term is the life of the latest-filed patent.

<sup>26</sup> See Table B, *supra*.

<sup>27</sup> 48 Fed. Reg. 53177 (Nov. 25, 1983).

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Exclusive agreements between Federal agencies and Bristol-Myers Squibb Co. for drug development is the public interest protected?* Hearing before the H. Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business, 102nd Cong. (1991), 350-377 at 354.

<sup>31</sup> 48 FR 53177.



research directed by the NIH staff.<sup>32</sup> HHS explained its rationale for granting a five-year extension, rather than the seven years requested by BMS, as follows:

[G]iven the fact that Bristol has already had almost five years of an exclusive market for cisplatin, and that the market for cisplatin is expected to expand dramatically in the next few years, we believe that five years of additional exclusivity is a sufficient incentive to induce Bristol to undertake the commitments which it has offered and is the best decision in the public interest.<sup>33</sup>

In another example involving a National Cancer Institute invention, the NIH licensed the HIV drug ddI (didanosine) to BMS. The license term was initially exclusive, but gave the NIH the option of making the license nonexclusive before the expiration of the NIH patents,<sup>34</sup> which the NIH exercised in 2001.<sup>35</sup> A term of exclusivity less than the life of patent did not chill investment - several companies competed for the license.<sup>36</sup> Around the time of the ddI license, the NIH frequently granted 10 year periods of exclusivity.<sup>37</sup>

Whatever exclusivity period the NIH ultimately negotiates, it must do so on a case-by-case basis, in order to fulfill Section 209's mandate that before granting an exclusive license, a federal agency determines that "the proposed scope of exclusivity is no greater than reasonably necessary to provide the incentive for bringing the invention to practical application." The apparent failure to do so here violates the Bayh-Dole Act.

*b. If the NIH had performed the analysis required by law, it would have concluded that even if an exclusive license was warranted, it would not need to be for the life of the patent.*

The factors bearing on the appropriate term of a license necessarily involve making estimates of such items as:

1. The government's investment in R&D and the development stage of the technology;
2. The costs of financing the additional trials and other research and development costs necessary to obtain FDA approval;
3. The cost to manufacturing the product; and

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<sup>32</sup> *Exclusive agreements between Federal agencies and Bristol-Myers Squibb Co. for drug development is the public interest protected?* Hearing before the H. Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business, 102nd Cong. (1991), 350-377 at 355.

<sup>33</sup> 48 FR 53177.

<sup>34</sup> *Id.*

<sup>35</sup> See National Institutes of Health Office of Technology Transfer, *Videx® Expanding Possibilities: A Case Study* (hereinafter, "Videx"), September 2003, available at <https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf>.

<sup>36</sup> *Id.*

<sup>37</sup> *Exclusive agreements between Federal agencies and Bristol-Myers Squibb Co. for drug development is the public interest protected?* Hearing before the H. Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business, 102nd Cong. (1991), 350-377 at 362.

#### 4. The expected profitability of the invention, over time.

If such analysis exists, it should have been provided to the public, in order to evaluate the proposed license terms. If such analysis does not exist, the NIH is not doing its job.

#### Profitability/Revenues

Yescarta, one of the two CAR therapies approved by the FDA, has been highly profitable for Gilead. As noted previously, Yescarta's list price is \$373,000 per patient. In the first six quarters since its initial approval, Yescarta has netted \$366 million, and its quarterly revenues from sales of Yescarta have increased significantly every quarter since its launch.<sup>38</sup> Kymriah's revenues have been doubling every six months, with \$58 million in revenue in the 2nd quarter of 2019.<sup>39</sup>

As government and private sector third party payers sort out reimbursement issues, company revenues are expected to increase.

#### R&D Costs

The estimated costs to develop CAR therapies are low relative to their profit yields. The FDA reported that the approval of Kymriah and Yescarta were based upon evidence from clinical trials consisting of 63<sup>40</sup> and 108<sup>41</sup> patients, respectively. Carl June, M.D., the lead investigator for Kymriah's clinical trials, has estimated the per-patient costs of CAR T clinical trials at roughly \$150,000 per patient,<sup>42</sup> making the total trial costs (\$10 to \$16 million before tax-credits and subsidies) trivial when compared to the profitability of such treatments.

Appellants noted in their comments that Yescarta and Kymriah were granted Orphan Drug status under the Orphan Drug Act of 1983, 21 U.S.C. §§ 360aa–360ee. Because the subject invention's field of use applies to similar rare disease indications, it is likely that it, too, will qualify for such status. The subsidies associated with Orphan Drug designation, including a 25% tax credit on clinical trials, must be taken into account when analyzing whether the scope of exclusivity is not greater than reasonably necessary to incentivize Kite/Gilead or some other company to commercialize the technology.

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<sup>38</sup> See Table 3, Appendix.

<sup>39</sup> See *id.*

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<https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states>

<sup>41</sup>

<https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM585388.pdf>.

<sup>42</sup> <https://www.keionline.org/30869>.

### Government Investment in the Technology

Gilead has benefitted from the government's investment in CAR T. Through its ownership of Kite, Gilead has assumed the benefit of at least three CRADAs between Kite and the NCI and seven exclusive license agreements, including the CRADA that led to the development of Yescarta. Many of those partnerships involve cell or gene therapies to treat cancer. Kite has acknowledged the role that public funding has played in developing its CAR therapies. Kite's 2015 SEC 10-k disclosure states: "A substantial portion of our research and development has been conducted by the NCI under the 2012 CRADA."<sup>43</sup>

Kite's relationship with the NCI is discussed in greater detail in Section C(4), *supra*.

### Cost of Manufacturing CAR Therapies

Dr. Walid Gellad, co-director of the Center for Pharmaceutical Policy and Prescribing at the University of Pittsburgh, called Kymriah's \$475,000 list price "outrageous" given the cost to manufacture it.<sup>44</sup>

Because the NIH declined to answer KEI's questions about the cost of manufacturing CAR T-cells, KEI must rely on the best available data. Dr. June once estimated that it costs about \$15,000 to manufacture Kymriah,<sup>45</sup> a CAR therapy that is similar to the licensed inventions. Our discussions with European manufacturers of CAR T cells suggest that even with current bottlenecks in markets for reagents and other inputs, cells can be manufactured for between €25,000 to €50,000 per treatment, with costs expected to fall dramatically. Since the NIH is conducting and funding CAR T trials, it clearly has relevant information it is declining to make available.

The disparity between the cost of manufacturing CAR therapies and the prices that Gilead and Novartis charge for them weigh against granting additional, broad exclusive rights in the technology to Gilead, since it is predictable that patients and employers, governments and insurance companies that pay for the treatments will be gouged by Gilead.

### 3. As far as KEI can determine, the NIH did not request the advice of the DOJ regarding whether the licenses would create or maintain a violation of federal antitrust laws.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, "[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law." 40 U.S.C. § 559(b)(1).

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<sup>43</sup> [https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k\\_20151231.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k_20151231.htm).

<sup>44</sup> <https://khn.org/news/cascade-of-costs-could-push-new-gene-therapy-above-1-million-per-patient/>.

<sup>45</sup> <https://khn.org/news/cascade-of-costs-could-push-new-gene-therapy-above-1-million-per-patient/>.

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. "Property" is defined at 40 U.S.C. § 102 to mean "any interest in property," with certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term "property" in Section 559 includes intellectual property rights such as patents.

**41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked the NIH whether it requested the advice of the U.S. Attorney General concerning the licenses. The NIH declined to answer, instead referring KEI to its past answers to the question.

On February 13, 2018, KEI emailed Dr. Lambertson and Karen Rogers, Acting Director of the NIH Office of Technology Transfer, asking whether NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests, as required by Section 559.

Ms. Rogers responded as follows:

"The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations."<sup>46</sup>

The NIH's statement about the applicability of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license "will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws." 35 U.S.C. § 211 provides that "[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]" The Bayh-Dole Act sets out the areas in which the statute "shall take precedence over any other Act

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<sup>46</sup> See Attachment J.

which would require a disposition of rights in subject inventions[,]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

Finally, by granting a fully-exclusive license in a federally-owned invention for life of patent, and allowing termination of the license only in narrow, vaguely-defined circumstances, the NIH is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

4. The licenses are unauthorized under 35 U.S.C. § 209(a)(4) because they “tend to substantially lessen competition or create or maintain a violation of Federal antitrust laws.”

Under 35 U.S.C. § 209(a)(4), before granting an exclusive license, a federal agency must ensure that “granting the license will not tend to substantially competition or create or maintain a violation of the Federal antitrust laws.”

The grant of two additional exclusive licenses in federally-sponsored CAR technologies to treat blood disorders to Gilead via Kite, which has already enjoyed an advantage over competitors through its relationship with the NCI, will tend to substantially lessen competition in the market of CAR T therapies to treat hematological disorders.

Since 2012, the NCI has entered into at least three CRADAs and seven exclusive licenses with Kite relating to CAR technologies and other cancer treatments. In its SEC filings, Kite touts its strong relationship with the NCI,<sup>47</sup> and the close relationship between Kite and the NIH/NCI was explored in a front page story in the New York Times titled “*Public Labs, Corporate Gains: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits.*”<sup>48</sup>

NIH’s partnerships with Kite are explained in greater detail below.

*The 2012 NCI-Kite CRADA*

Gilead acquired Kite in October 2017 for \$11.2 billion. In so doing, Gilead acquired the rights to Yescarta,<sup>49</sup> a CAR therapy that benefited heavily from federal funding. The technology behind

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<sup>47</sup> See, e.g.,

<https://www.sec.gov/Archives/edgar/data/1510580/000151058017000003/kite20161231-10k.htm> (“Our strong relationship with the NCI is bolstered by our President and Chief Executive Officer’s relationship with Dr. Rosenberg of the NCI.”).

<sup>48</sup> Matt Richtel and Andrew Pollack, *Public Labs, Corporate Gains: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits*, N.Y. Times, Dec. 19, 2019, available at <https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html>.

<sup>49</sup> <https://www.sec.gov/Archives/edgar/data/882095/000088209518000008/a2017form10-k.htm>



Yescarta was developed in NCI labs pursuant to a CRADA executed in 2012 between NCI and Kite, with Dr. Steven A. Rosenberg as the Principal Investigator.<sup>50</sup>

#### *The 2016 NCI-Kite CRADAs*

Gilead likely will obtain even more rights in CAR therapies to treat B cell lymphomas through a second CRADA executed between Kite and the NIH in 2016. CRADAs typically grant the industry-collaborator the option of retaining exclusive rights in any intellectual property developed pursuant to the agreement. On January 4, 2016, Kite entered into a CRADA with NIH to develop anti-CD19 car therapies to treat B cell lymphomas and leukemias. The CRADA will expire January 4, 2021 and “will focus on the development of next-generation CAR programs directed against other novel antigens for the treatment of B cell lymphomas and leukemias.”<sup>51</sup>

In June 2016, Kite entered into a CRADA with the NCI to pursue clinical development of “T-cell receptor (TCR) product candidates directed against human papillomavirus (HPV)-16 E6 and E7 oncoproteins for the treatment of HPV-associated cancers.”<sup>52</sup>

#### *Exclusive Licenses between Gilead (through Kite) and NCI*

In 2017, NIH proposed a broad license to Kite in an autologous CAR immunotherapy targeting the CD30 antigen, for the treatment of diseases such as Hodgkin lymphoma, Non-Hodgkin lymphoma, and diffuse large B cell lymphoma, the same indications as the licensed invention.<sup>53</sup>

In addition, Gilead now owns exclusive licensing rights to a slew of government-financed cell or gene therapies, as the successor in interest to the following exclusive licenses with NIH.

**Table 2: NIH Exclusive Licenses to Kite in Government-Owned Inventions**

<u>Date</u>	<u>Terms</u>	<u>Invention</u>
April 11, 2013	Exclusive, worldwide, life of patent <sup>54</sup>	“a CAR-based product candidate that targets the EGFRvIII antigen for the treatment of brain cancer, head and neck cancer and melanoma, and a TCR-based product candidate that targets the SSX2 CTA for the treatment of head and neck cancer, hepatocellular carcinoma, melanoma, prostate cancer, and sarcoma”
May 29, 2014	Exclusive, worldwide,	“TCR-based product candidates that target the NY-ESO-1 antigen for the treatment of any NY-ESO-1 expressing cancers”

<sup>50</sup> See Kite Pharma, Inc.’s Amended Answer and Countercl. para. 19, *Juno Therapeutics, Inc. et al. v. Kite Pharma, Inc.*, No. CV 17-7639-SJO-KSX (C.D. Cal. March 29, 2018).

<sup>51</sup> [https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k\\_20151231.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k_20151231.htm)

<sup>52</sup> For more information about the NIH-Kite CRADAs, see Table 5, Appendix.

<sup>53</sup> For a list of all notices of proposed exclusive licenses to Kite, see Table 4, Appendix.

<sup>54</sup> [https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q\\_20150930.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q_20150930.htm)

	life of patent <sup>55</sup>	
June 2, 2014	Exclusive, worldwide, life of patent. <sup>56</sup>	"TCR-based product candidates that target the NY-ESO-1 antigen for the treatment of any NY-ESO-1 expressing cancers"
December 31, 2014	Exclusive, worldwide, life of patent <sup>57</sup>	"TCR-based product candidates that target HPV antigens E6 and E7 of the HPV subtype 16"
October 1, 2015	Exclusive, worldwide, life of patent <sup>58</sup>	"TCR-based product candidates directed against MAGE A3 and A3/A6 antigens for the treatment of tumors expressing MAGE"
July 2016	Exclusive, worldwide, term not stated <sup>59</sup>	"Fully human anti-CD19 chimeric antigen receptor-based product candidate directed against B-cell malignancies"
September 2016	Exclusive, worldwide, term not stated <sup>60</sup>	"T-cell receptor (TCR) based product candidates for the treatment of tumors expressing mutated KRAS antigens"

#### *Gilead's Market Concentration of Gene Therapies to Treat Hematological Cancers*

Gilead has acquired vast rights in CAR T and other gene therapies to treat hematological cancers. It lists the following product candidates as part of its technology suite:

#### **Excerpt from Gilead's 2018 SEC 10-k Filing**

*Product Candidates for the Treatment of Hematology/Oncology*

<sup>55</sup> [https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q\\_20150930.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q_20150930.htm).

<sup>56</sup> [https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k\\_20151231.htm](https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k_20151231.htm).

<sup>57</sup> <https://www.sec.gov/Archives/edgar/data/1510580/000151058017000011/kite10q6-30x17.htm>.

<sup>58</sup> <https://www.sec.gov/Archives/edgar/data/1510580/000151058017000011/kite10q6-30x17.htm>.

<sup>59</sup>

<https://www.biospace.com/article/releases/kite-pharma-announces-exclusive-license-with-nih-for-fully-human-anti-cd19-chimeric-antigen-receptor-car-product-candidate-to-treat-b-cell-malignanc/>.

<sup>60</sup>

<https://www.biospace.com/article/releases/kite-pharma-announces-exclusive-license-with-nih-for-multiple-neoantigen-directed-t-cell-receptor-tcr-product-candidates-to-treat-solid-tumors-expre/>.

Product Candidates	Description
<b>Products in Phase 3</b>	
Axicabtagene ciloleucel	Axicabtagene ciloleucel is being evaluated for the treatment of second line diffuse large B-cell lymphoma (DLBCL).
<b>Products in Phase 2</b>	
Axicabtagene ciloleucel	Axicabtagene ciloleucel is being evaluated for the treatment of indolent non-Hodgkin lymphoma. Axicabtagene ciloleucel is also being evaluated for the treatment of DLBCL in combination with anti-PD-L1 mAB and first line DLBCL.
Tirabrutinib	Tirabrutinib, a BTK inhibitor, is being evaluated for the treatment of B-cell malignancies.
KTE-X19	KTE-X19, a CAR T cell therapy, is being evaluated for the treatment of mantle cell lymphoma and adult and pediatric acute lymphoblastic leukemia.
<b>Products in Phase 1</b>	
KITE-718	KITE-718, a MAGE A3/A6, is being evaluated for the treatment of solid tumors.

### *Consequences of Undue Market Concentration*

Undue market concentration will have negative consequences for American cancer patients and taxpayers, employers, and others who pay for such treatments.

The two CAR therapies to receive FDA approval, Yescarta and Kymriah, start at \$373,000 and \$475,000, respectively, and those prices are exclusive of hospital costs.

The high launch prices of CAR therapies provide a compelling reason not to grant further market concentration in these products to a company like Gilead.

Price and market exclusivity are directly linked: According to healthcare policy experts, “[t]he most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity[.]”<sup>61</sup>

Evidence of Gilead’s own price-setting strategies confirms this statement.

Gilead’s pricing strategy for Sovaldi was more focused on maximizing revenue through expanding its market share than it was on broadening patient access, according to a 2015 Senate Finance Committee investigation, which concluded as follows:

<sup>61</sup> Kesselheim, et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, JAMA, August 23, 2016.

Over the eight months Gilead spent determining the price of Sovaldi, the company repeatedly made clear its primary focus was outmaneuvering potential competitors to ensure its drugs had the greatest share of the market, for the highest price, for the longest period of time.<sup>62</sup>

The report found that Gilead could have made a profit on Sovaldi by charging \$55,000 for a 12-week course of treatment, yet chose to charge \$84,000, a price that would deliver higher profits but result in fewer patients being treated.<sup>63</sup>

Granting the exclusive licenses to a competitor, rather than to Gilead, would have introduced new competitors into the market, and could have helped bring prices down.

NCI has not articulated a logical rationale for concluding, over our objections, that giving additional rights in CAR to Gilead would be consistent with 35 U.S.C. § 209(a)(4). In its final determinations, NCI considers only two facts: the existence of a single competitor, Novartis, in the relevant market, and the fact that the licenses do not extend to all fields of use.

The NIH's reliance on the existence of one other competitor in the market is misplaced. In NIH's line of reasoning, a license will satisfy 35 U.S.C. § 209(a)(4) so long as there is one other manufacturer of a similar therapy in the same field of use. Yet 35 U.S.C. § 209(a)(4) does not ask whether a license will eliminate all other competitors. Rather, it prohibits an exclusive license that "will tend to *substantially lessen* competition[.]"

If NIH does not consider itself equipped to engage in a legitimate analysis of the potential anticompetitive effects of its licensing decisions, that would provide a compelling reason for it to comply with 40 U.S.C. § 559, which requires federal agencies to seek the advice of the U.S. Attorney General when disposing of government property, including intellectual property rights. As a matter of practice, the NIH does not seek out such advice.

#### 5. The NIH's lack of transparency regarding the licenses impeded the public's right to comment.

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely submitted comments. 35 U.S.C. § 209(e).

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<sup>62</sup> Senate Finance Committee, *Executive Summary, The Price of Sovaldi and its Impact on the U.S. Healthcare System*, December 2015, available at <https://www.finance.senate.gov/imo/media/doc/11%20SFC%20Sovaldi%20Report%20Executive%20Summary.pdf>.

<sup>63</sup> S. Rep. No. 114-20, at 20-22 (2015), available at [https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf).

In order for the public to meaningfully participate in the notice-and-comment process, it must have basic information about the licenses. Because the NIH failed to provide sufficient information in its federal register notices, KEI was required to request that information directly from the agency. It did so on July 12, 2019, when KEI Researcher Claire Cassedy emailed Dr. Lambertson a list of 10 questions related to the criteria for granting an exclusive license. The questions addressed issues such as the stage of research and development of the invention, whether any clinical trials were associated with the technology, the duration of the licenses, whether NIH sought the advice of the Attorney General under 40 U.S.C. § 559, and how the NIH would negotiate license terms to ensure access to the resultant products on reasonable terms.<sup>64</sup>

Dr. Lambertson refused to answer seven of the 10 questions, erroneously asserting that the questions “either ha[d] been answered previously or [were] not related to the criteria . . . regarding a decision by a federal agency to grant an exclusive license.”<sup>65</sup>

KEI reviewed the NIH’s past answers to KEI’s questions regarding prospective licenses to determine whether the NIH had answered them previously. It had not. The NIH refused to answer questions about government funding on the basis that it purportedly did not have access to such information or the information was not within its purview. In response to past questions about the duration of a prospective license, the NIH asserted that the term had yet to be negotiated or was confidential. And the NIH has asserted erroneous objections that KEI’s questions seek irrelevant information and that the agency is not required to seek the advice of the Attorney General under 40 U.S.C. § 559.

None of the NIH’s justifications for its lack of transparency pass muster. KEI’s questions bear directly on the criteria governing government licenses of federally-owned technologies. When taxpayers invest tens of billions of dollars annually in biomedical research and development, the NIH should be able to tell the American public how much of its taxpayer dollars are used to finance the development of a particular technology.

The NIH should not promise confidentiality to prospective licensees with respect to licensing terms that bear directly on whether the scope of a license is not greater than reasonably necessary to incentive the commercialization of government-owned technology, a matter on which the public is entitled to comment.

Moreover, licensing terms such as the duration of a license and royalty payments to the NIH are often disclosed by companies such as Kite in their SEC filings. In a 2017 quarterly SEC report, for example, Kite disclosed a number of NIH exclusive licenses that were set to “expire upon expiration of the last patent contained in the licensed patent rights[.]”<sup>66</sup>

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<sup>64</sup> See Attachment A.

<sup>65</sup> See *id.*

<sup>66</sup> <https://www.sec.gov/Archives/edgar/data/1510580/000151058017000011/kite10q6-30x17.htm>.

In any event, when it comes to government licensing of publicly-financed technologies, the public's right to know the terms of the licenses and what the public has spent on the inventions outweighs any private interest in non-disclosure. To maintain that the NIH need not disclose to the public information that is directly relevant to the appropriateness of the licenses would be to render the public's right of comment at 35 U.S.C. § 209(e) a nullity.

6. The NIH has not implemented objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

The PHS's licensing policy is governed by the following principle, among others:

"PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."<sup>67</sup>

In our July 29, 2019 comments, we asked that the NIH not grant the licenses unless efforts were made to ensure access in developing countries.<sup>68</sup>

Access to CAR therapies in developing countries is effectively nonexistent today, outside of China. All of the individuals and groups who cosigned the comments and join this appeal believe that governments should license intellectual property in a way that enables more equal access. How we treat patients in low-income countries goes to the character of the people who manage the NIH and its technology transfer offices. There are at least five billion people in the world who live in resource-poor countries, not even counting China, and who have at best extremely unequal access, if any, to the new NIH-funded cell and gene therapies. Someone working in a public institution should see this is a real problem, and one that deserves some actual attention.

We object to any licenses that do not satisfy PHS's governing licensing principle of promoting access in developing countries.

It would be quite simple to at least ask the licensee to provide a plan, made public so there is some accountability, as to how access will be extended to countries with per capita incomes less than 30 percent of the United States. Not even making this part of the negotiation is appalling and inconsistent with PHS's own stated licensing policies.

#### **D. CONCLUSION**

For all of the reasons stated above, appellants request that the NIH reverses its decision to proceed with the licenses at issue and reopen the licenses to competitive bidding, unless they

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<sup>67</sup> PHS, *United States Public Health Service Technology Transfer Manual*, Chapter No. 300, PHS Licensing Policy, available at <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300-policy.pdf>.

<sup>68</sup> See Attachment F.



include the public interest safeguards referred to in our submitted comments and the NIH seeks and obtains the antitrust advice from the Attorney General, who confirms that the licenses will not create or maintain a situation inconsistent with federal antitrust laws.

We request a hearing on this appeal.

Sincerely,

Knowledge Ecology International  
Social Security Watch  
Universities Allied for Essential Medicine  
Union for Affordable Cancer Treatment  
Clare Love

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## APPENDIX

**Table 3: Yescarta and Kymriah Sales in Millions of U.S. Dollars**

	2019 Q1	2018 Q4	2018 Q3	2018 Q2	2018 Q1	2017 Q4
<b>Yescarta</b>	\$96	\$80	\$75	\$68	\$40	\$7
<b>Kymriah</b>	\$45	\$28	\$20	\$16	\$12	\$7

**Table 4: Previous Federal Register Notices Listing Kite as Prospective Licensee**

Date	Notice Title and URL
01/24/ 2012	"Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer" Link: <a href="https://www.federalregister.gov/d/2012-1383">https://www.federalregister.gov/d/2012-1383</a>
03/25 2014	"Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer" Link: <a href="https://www.federalregister.gov/d/2014-06412">https://www.federalregister.gov/d/2014-06412</a>
10/16/ 2014	"Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans To Treat Cancer" Link: <a href="https://www.federalregister.gov/d/2014-24502">https://www.federalregister.gov/d/2014-24502</a>

06/26/ 2015	<p>"Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers"</p> <p>Link: <a href="https://www.federalregister.gov/d/2015-15657">https://www.federalregister.gov/d/2015-15657</a></p>
08/17/ 2016	<p>"Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer"</p> <p>Link: <a href="https://www.federalregister.gov/d/2016-19549">https://www.federalregister.gov/d/2016-19549</a></p>
10/05/ 2016	<p>"Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers"</p> <p>Link: <a href="https://www.federalregister.gov/d/2016-24030">https://www.federalregister.gov/d/2016-24030</a></p>
12/20/ 2017	<p>"Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer"</p> <p>Link: <a href="https://www.federalregister.gov/d/2017-27416">https://www.federalregister.gov/d/2017-27416</a></p>

**Table 5: Previous CRADAs Between the NIH and Kite**

Date	CRADA Title and Number
08/31/ 2012	<p>"Cooperative Research and Development Agreement for the Development of NCI Proprietary Peripheral Blood Autologous T Cell Therapies Using Genetically Modified Peripheral Blood Lymphocytes that Express NCI Proprietary T-cell Receptors and/or Chimeric Antigen Receptors for Use in Immunotherapy for Patients with Metastatic Cancer, Utilizing the Expertise of Kite Pharma in the Development and Manufacturing of Cancer Immunotherapies"</p> <p>Number: C-064-2012/0</p>
06/09/ 2016	<p>"Clinical Development of T Cell Receptor Gene Therapy Targeting HPV-16 E6 and E7 for HPV-Associated Cancers"</p> <p>Number: C-070-2016/0</p>
01/04/ 2016	<p>"Clinical Evaluation of NCI-hCD19-CAR, a CD19-Targeting Chimeric Antigen Receptor (CAR) for the Treatment of B Cell Lymphoma and B cell Leukemia, and the Development of Novel CARs Targeting B Cell Malignancies"</p> <p>Number: C-017-2016/0</p>



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**From:** rohrbaum@od.nih.gov [rohrbaum@od.nih.gov]  
**Sent:** 8/19/2020 7:25:05 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** Re: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Might be better to [b5]  
[b5] You could [b5]  
[b5] I think [b5]

Sent from my iPhone

On Aug 19, 2020, at 3:04 PM, Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:

Hi Mark,

Can you spare a few minutes to chat about this today or tomorrow?

I'm available between 4:30 and 5 today, then again tomorrow before 10:30 and after 2.

I can call your mobile [b6] or a different number if you prefer.

Thanks,

Mike

**From:** Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Sent:** Monday, August 17, 2020 8:37 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <vathyams@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Hi Mark,

Checking back on this.

I'm out of town now and back on Wed.

Thanks,

Mike  
Michael R. Mowatt, Ph.D.  
Director, Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services

REL0000025227

+1 301 496 2644

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**From:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Sent:** Wednesday, August 12, 2020 1:02:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Cc:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark and Surekha,

I reviewed the FRN (attached) and noticed that the comment period ended on 27 Jul, i.e., 3 days before the date of Mr. Love's letter (attached).

**b5**

Please let me know if you support this approach or if you recommend an alternative.

I will share the proposed communication with Jill Harper after we finalize our review.

Thanks,

Mike

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Sent:** Tuesday, August 4, 2020 4:06 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <[MMOWATT@niaid.nih.gov](mailto:MMOWATT@niaid.nih.gov)>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Alternatively,

**b5**

**b5**

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, August 4, 2020 4:02 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <[MMOWATT@niaid.nih.gov](mailto:MMOWATT@niaid.nih.gov)>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Subject:** RE: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

REL0000025227

I don't recall [b5] would suggest:

b5

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**From:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Sent:** Tuesday, August 4, 2020 3:40 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Cc:** Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>; Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mark,

I've confirmed [b5]  
I'll work with you to develop a draft response.

We agreed to [b5]  
[b5]

Thanks,

Mike

---

**From:** Harper, Jill (NIH/NIAID) [E] <[jharper@niaid.nih.gov](mailto:jharper@niaid.nih.gov)>  
**Sent:** Thursday, July 30, 2020 8:39 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>; Vathyam, Surekha (NIH/NIAID) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Cc:** Haskins, Melinda (NIH/NIAID) [E] <[haskinsm@mail.nih.gov](mailto:haskinsm@mail.nih.gov)>; Sullivan, Fantasia (NIH/NIAID) [C] <[fantasia.sullivan@nih.gov](mailto:fantasia.sullivan@nih.gov)>; Fowler, Karen (NIH/NIAID) [C] <[fowlerk@niaid.nih.gov](mailto:fowlerk@niaid.nih.gov)>; Auchincloss, Hugh (NIH/NIAID) [E] <[auchinclossh@niaid.nih.gov](mailto:auchinclossh@niaid.nih.gov)>  
**Subject:** Fwd: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Mike and Surekha, please see below and attached, and let's discuss early next week.

Thanks,  
Jill

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**From:** "Fauci, Anthony (NIH/NIAID) [E]" <[afauci@niaid.nih.gov](mailto:afauci@niaid.nih.gov)>  
**Date:** Thursday, July 30, 2020 at 7:51:28 PM  
**To:** "Harper, Jill (NIH/NIAID) [E]" <[jharper@niaid.nih.gov](mailto:jharper@niaid.nih.gov)>

REL0000025227



**Cc:** "Conrad, Patricia (NIH/NIAID) [E]" <[conradpa@niaid.nih.gov](mailto:conradpa@niaid.nih.gov)>, "Barasch, Kimberly (NIH/NIAID) [C]" <[kimberly.barasch@nih.gov](mailto:kimberly.barasch@nih.gov)>

**Subject:** FW: Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Jill:

Please look into this and take care of it.

b5

Thanks,

Tony

**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Sent:** Thursday, July 30, 2020 11:59 AM

**To:** Fauci, Anthony (NIH/NIAID) [E] <[AFAUCI@niaid.nih.gov](mailto:AFAUCI@niaid.nih.gov)>

**Cc:** Paul Davis <[pdavisx@gmail.com](mailto:pdavisx@gmail.com)>; Sawyer, Eric <[ERICLSAWYER@gmail.com](mailto:ERICLSAWYER@gmail.com)>; Brook Baker <[b.baker@northeastern.edu](mailto:b.baker@northeastern.edu)>; Thiru Balasubramaniam <[thiru@keionline.org](mailto:thiru@keionline.org)>; Morten, Christopher <[christopher.morten@nyu.edu](mailto:christopher.morten@nyu.edu)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Peter Maybarduk <[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org)>; lumbasia@citizen.org; Luis Villalon <[info@innovarte.cl](mailto:info@innovarte.cl)>; Merith Basey <[merith@essentialmedicine.org](mailto:merith@essentialmedicine.org)>; lpma75@gmail.com; Gopa Kumar <[kumargopakm@gmail.com](mailto:kumargopakm@gmail.com)>; Sangeeta <[sangeeta@twnetwork.org](mailto:sangeeta@twnetwork.org)>; Umutyana Rugege <[rugege@section27.org.za](mailto:rugege@section27.org.za)>; Ngqabutho Mpofu <[ngqabutho.mpofu@mail.tac.org.za](mailto:ngqabutho.mpofu@mail.tac.org.za)>; Manuel MARTIN <[Manuel.MARTIN@geneva.msf.org](mailto:Manuel.MARTIN@geneva.msf.org)>; Yuanqiong HU <[Yuanqiong.HU@geneva.msf.org](mailto:Yuanqiong.HU@geneva.msf.org)>

**Subject:** Letter asking that NIAID not grant exclusive rights for HIV patent license in South Africa, India, and other low income countries

Dr. Fauci,

Attached is a letter from several individuals and groups, asking that NIAID not grant exclusive rights in a HIV patent license for South Africa, India and other low income countries.

The license is to RNAceuticals, a firm without a web page. The technology is for N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains.

This letter addresses a narrow issue, the geographic scope of the license, and it asks that exclusivity does not extend to countries like South Africa and India, that have per capita incomes less than 30 percent of the United States.

Among the groups signing are the leading patient group for persons living with HIV in South Africa, where an estimated 19 percent of persons from 19 to 49 are living with HIV, and patient advocacy groups working in Southeast Asia, India, Brazil, Chile, Mexico, Ecuador, Argentina, Colombia, and Guatemala, as well as several US and globally based health groups and patient advocates.

Jamie

--

James Love. Knowledge Ecology International

U.S. Mobile +1.202.361.3040

U.S. office phone +1.202.332.2670

<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

<85 FR 41607 (2020-14836).pdf>

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<Letter2Fauci.RNAceuticals.License.Geographic.Scope.30July2020.pdf>  
<Love, J, et al. DRAFT 200812.docx>